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ABSTRACT

This publication reports on the proceedings of a symposium convened for the purpose of examining the relationship between medical technology and health care costs. The proceedings of this symposium are comprised by a series of papers that were presented at the conference covering a variety of topics, including statistical evidence of the relationship between health care costs and medical technologies, case studies on the development, introduction and use of technology, and recommendations concerning relevant public policy issues. (JD)

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE • Public Health Service

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Stuart H. Altman and
Robert Blendon,
Editors

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The Sun Valley Forum on National Health, Inc.

The Sun Valley Forum on National Health is a nonprofit educational organization incorporated in 1970 under the laws of Idaho. The purpose of the Forum is to work toward the improvement of the health of Americans and of the health care delivery system. The Forum seeks this objective through educational activities—the sponsorship of symposia, conferences and lectures and the preparation and publication of books, papers and reports. Governed by a board of directors of medical professionals and lay leaders, the Forum endeavors to carry out its programs at the highest possible level of quality and excellence.

Activities of the Forum center in Sun Valley, a facility well suited and equipped for sustained serious discussion. The Forum's symposia bring together leaders and experts to meet, to share ideas, and to review expert papers on aspects of the nation's health problems. Symposium participants include professionals in all health related fields as well as other persons associated with or interested in health affairs, such as representatives of consumers, businessmen, public officials and educators.

Since its founding in 1970 the Forum has held seven such symposia. These were major undertakings, each lasting six days, involving about 30 participants, concentrating on a group of specially commissioned working papers, and each producing a final report of the symposium.

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Foreword

The growth of technology in health care has been a phenomenon reflective of both the capacity of modern science and medicine to develop increasingly sophisticated methods to diagnose and treat illness on the one hand, and the American commitment to the health of its people on the other. The rapidly rising costs of health care in the United States has become a critical issue to legislators, policy makers, planners, and researchers alike, and efforts to curb these rising costs must be matched by efforts to understand the complex political, social, and economic factors underlying medical technologies and health care costs.

In August 1977, a symposium entitled "Medical Technology: The Culprit Behind Health Care Costs?" was convened by the Sun Valley Forum on National Health, Inc., for the purpose of examining the relationship between medical technology and health care costs. The proceedings of this symposium are comprised by a series of papers that were presented at the conference covering a variety of topics, including statistical evidence of the relationship between health care costs and medical technologies, case studies on the development, introduction and use of technology, and recommendations concerning relevant public policy issues.

The National Center for Health Services Research and the Bureau of Health Planning are pleased to publish these proceedings in the hope that the debate contained within them will assist all who are interested and involved in health care in the United States to better understand the issues surrounding a complex topic of immense importance.

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June 1979

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Dr. Robert J. Blendon—Biographical sketch

Dr. Robert J. Blendon is Vice President of the Robert Wood Johnson Foundation. He previously served in the Department of Health, Education, and Welfare, as Special Assistant for Policy Development in Health and Scientific Affairs to both the Assistant Secretary and Deputy Undersecretary of the Department. Dr. Blendon is a graduate of the School of Business, The University of Chicago, with a master's degree in Business Administration. In addition, he holds a doctoral degree from the School of Public Health, Johns Hopkins University, where his principal attention was directed toward health services administration and research. Prior to his HEW appointment, Dr. Blendon served as Assistant Director for Planning and Development, Office of Health Care Programs, Johns Hopkins School of Medicine; and Assistant Professor, Department of Medical Care and Hospitals, at the School of Public Health.

Stuart H. Altman—Biographical sketch

Stuart H. Altman, Dean of The Florence Heller Graduate School at Brandeis University, is an economist whose research interests are primarily in the area of Federal health policy. Between 1971 and 1976, Dr. Altman was the Deputy Assistant Secretary for Health Planning and Evaluation, Department of Health, Education, and Welfare. While serving in that position, he was one of the principal contributors to the development and advancement of the Administration's National Health Insurance proposal. From 1973 to 1974, he was also Deputy Administrator at the Cost of Living Council where he was responsible for developing the Council's program on cost containment. He is currently advisor to the Office of Technology Assessment, the Josiah Macy Foundation, and the Health Care Financing Administration, HEW. He is a member of the Institute of Medicine and serves on the board of the Robert Wood Johnson Foundation's Clinical Scholars Program. Dr. Altman is chairman of the board of the University Health Policy Consortium located at Brandeis University. Dr. Altman has an M.A. and Ph.D. degree from UCLA (1964) and taught at Brown University (Associate Professor, 1966–1970) and the Graduate School of Public Policy (University of California, Berkeley, 1976–77).

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Introduction

Stuart Altman and Robert Blendon

This proceedings has been written in response to the growing public concern about the huge increases in medical care costs. One part of this concern has been related to whether or not medical technology has caused this sharp rise. If it has, many have asked, should not the public take some form of action to slow the growing cost of today's new medical techniques?

The volume addresses the relationship between medical technology and health care costs. The 16 papers presented here grew out of a symposium conducted by the Sun Valley Forum on National Health in August 1977. The purpose of this Forum was twofold: first, to examine the evidence relating to whether the introduction of various types of medical technologies has been an important factor in the rapid rise in health care costs over the past decade; second, to review the need for and to discuss the implications of various proposed public sector strategies for limiting future cost increases by controlling the introduction of expensive medical technologies.

The discussion was particularly timely, because recently most public opinion polls and government announcements on health care have singled out the rapid escalation of costs as the most critical health care problem in the nation, with many observers believing that no substantial expansion of health care benefits via national health insurance can be forthcoming until a solution is found for controlling these costs. One particular component—the utilization of high cost medical technologies—has been singled out by many public figures and researchers as a key factor in the cost increase problem.

In response to these concerns, several units within the federal government and a number of independent analysts have proposed greater public sector intervention in the health sector for purposes of controlling costs. Of particular interest to some is the need for governmental approval of expensive new medical services or devices, based on demonstrated effectiveness and safety, prior to their introduction. This and other proposed interventions are likely to be given serious consideration by the Administration and the Congress in the next few years.

The need for a private group to examine the role of technology in the escalation of health care costs

At present, the United States is widely recognized as having the most technologically sophisticated system of medicine to be found anywhere in the world. Since World War II we have, as a nation, invested an impressive amount of tax dollars into the advancement of biomedical research, and a bewildering array of technologic advances has emerged from this investment. Where ultimate technologies have been introduced, such as polio vaccine, major cost reductions and profound changes in health status have followed. Where no final biological answer has as yet been discovered—as with cancer or coronary heart disease—expensive technologies like cobalt therapy or coronary care units have been developed with less clear-cut resulting benefits. However, until recently the health care system has operated in such a way that any new technology could be introduced if a licensed physician believed that it was of benefit to his/her patient. By and large, such decisions have been made irrespective of their cost-implications or even unequivocal validation. With drugs, of course, such a laissez-faire attitude disappeared many years ago.

However, with the continuous rise in health care costs, there has been a perceivable shift in American attitudes about technology. This can be seen in: (1) attention given by the media to the costliness of the new wave of medical technologies, most recently the computerized tomography (CT) scanners; (2) the number of professional conferences and committees established to examine the possible negative role of medical technologies; and (3) the considerable recent activity, within various legislative branches, devoted to the design of ambulatory care mechanisms to stem the increased use of in-hospital, high-technology care. Concern about the possible adverse effects of technology in general, and medical technology in particular, has become a regular part of the public dialogue. More importantly, and perhaps for the first time in this country, various groups are suggesting either slowing down or even temporarily halting the introduction of new medical technologies.

The growing discussion about the desirability of continued investment in coronary care units is a prototypical example of this phenomenon. Studies of coronary care units have shown the average cost per patient treated in these units to be nearly double the cost of other hospital patients. From this it has been estimated that the present additional cost of intensive care for patients hospitalized with acute coronary disease is nearly half a billion dollars per year. The question increasingly being raised is whether the effectiveness of these units in preventing deaths is sufficient to justify the required national investment.

The whole question of the relationship between health care costs and medical technology is a complex one. As suggested by the coronary care example, any public sector decisions in this area could have long-term effects on both the cost and quality of health care provided in this country. Because this is such a difficult issue, there is need for a variety of groups, both public and private, to examine systematically the question of what costs are imposed by new technologies, and to make a careful assessment of the actual need, feasibility, and possible long-term impact of various proposed public sector controls.

The issues to be examined

By necessity we have been forced to exclude from this volume many facets of the problem of medical technology in American life. This in no way implies a lack of recognition of their importance, but rather reflects the need to focus adequately on the narrower but complex issue of the relationship between health care costs and medical technologies. The disturbing aspects of technology that will be excluded from consideration include: (1) that the medical care system is out of control—that the development and dissemination of new medical technologies happen too fast for us to comprehend their impact on our lives; (2) that these technologies have not lived up to our expectations of their benefit to individual patient care; (3) that the age of technologies is forcing us to face unanswerable questions about the nature of life, in such instances as the Karen Anne Quinlan case or cloning; and (4) that these technologies have led to a dehumanization of health care by replacing what rightfully ought to be a more personally caring service.

Many of these excluded issues are currently being addressed by such groups as the Institute of Medicine of the National Academy of Sciences, the National Research Council of the Assembly of Engineering, and the Institute of Society, Life and Ethics. Each is, quite appropriately, subject matter for a separate in-depth investigation.

Outline of proceedings and summary of findings

The term "medical technology" is a very general one which has many meanings depending on the user. In the world of medicine it can encompass anything from sterilized bandages to open-heart surgery. In order to focus this book, the discussion of this term was narrowed to include only those technologies that appear to have a high potential for affecting health care costs. For purposes of discussion, these technologies have been subdivided into three categories:

1. Those that require large capital expenditures to purchase—for example, the CT scanner;
2. Those that do not require large capital expenditures or high costs of attendant personnel, but have potential for enormous utilization because of the large number of providers who will have ready access to them—for example, certain surgical procedures or common laboratory tests; and
3. Those with high personnel costs—for example, renal dialysis. Other technologies, which are not believed to have a significant impact on the cost of medical care or which do not directly involve patient care, are not specifically addressed.

The first section of the volume provides an overall perspective on the main issue addressed by the Conference: Has medical technology significantly impacted on the per-unit costs of health care and on national expenditures for these services? As a prologue to this section *Blendon and Moloney* trace the national events of the last decade. They point to the fact that "the Johnson administration quite deliberately avoided asking the country to make a choice between continuing the war in Vietnam and enacting the social programs of the Great Society." They maintain that the decision to pursue both goals led to a major inflationary spiral. Between 1965 and 1972 medical care costs increased by almost 50 percent and hospital charges by 129 percent. During this period, health expenditures grew from 2 to 8 percent of the federal budget. Efforts at cost control were aimed initially at calling for voluntary, self-imposed restraints and at improving the management of the nation's hospitals. When these efforts did not succeed, the government attempted to regulate the system through limiting capital expenditures and through utilization control. Despite these interventions, health expenditures continued to increase faster than expenditures in other segments of the economy. Only the wage and price controls instituted by the Nixon administration significantly changed the rate of expenditures of health care in the United States after the enactment of Medicare and Medicaid.

Altman and Wallack then evaluate the extent to which technology can be implicated in today's health care cost problem. They point to the conflicting findings on the role technology has played in increasing costs. They cite the testimony of Clifton Gaus before the President's Biomedical Research Panel concluding that ". . . new health care technology is a major cause of the large yearly increases in national health expenditures." One year later Selma Mushkin and her colleagues from the Public Services Laboratory of Georgetown University reported that "biomedical research on balance reduces health outlays rather than increases [them]." In presenting the cases for and against technology, Altman and Wallack caution the reader about the many methodological limitations that have prevented refined measurement techniques from being used to evaluate the impact of technology. Nevertheless, the authors conclude that the evidence suggests that "the spread of complex technologies to more hospitals and the development and deployment of expensive diagnostic and therapeutic equipment leaves little doubt that the cost of a day or a stay in a hospital has risen significantly in the past 15 years because of technological advances and diffusion." The authors also question whether other savings could have been large enough to offset such hospital costs increases in an estimate of the impact of technology on total national expenditures for health services.

Scitovsky, in her paper, attempts to demonstrate the effect, not of major technological innovations, but of the ancillary services used to treat common conditions. Referring to the cost-of-illness studies conducted at the Palo Alto Medical Research Foundation in the periods 1951–1964–1971, she notes that, "with minor exceptions, cost raising changes in treatment outweighed cost-saving changes . . . so that the net effect of changes in treatment were generally cost-raising." She goes on to say that "we found that the main cost-raising factor in both periods was the steady increase in the use of ancillary services such as laboratory tests and X-rays, both in and out of the hospital." Through a series of estimates, she concludes that between $4.8 and $6.7 billion may have been spent for outpatient laboratory tests and X-rays in 1975 accounting for 5–6 percent of total personal health care expenditures.

Using the Massachusetts General Hospital as an example of the effect of technology on rising hospital costs, *Sanders* notes that while annual patient-days changed little from 1965 to 1975, 1,862 new employees were added. This coincided, he said, with the introduction of ten intensive care units. He adds that new roles were needed to service the equipment embodied in the technology. He points to the Department of Inhalation Therapy at the MGH as a particularly cogent example of growth. That department grew from four technicians on a budget of $32,333 in 1959, to 70 technicians with a budget of $884,000 in 1976. He concludes that "at least in the tertiary care setting, technology can indeed be 'blamed' for a substantial portion of rising hospital costs." The author points to the forces both internal and external to the health care system that have encouraged extensive employment of technology by the hospitals. Among those forces is a public governed by the belief that technology is a good thing, the cost reimbursement system of the government and other third party payers, and the lack of incentives for consolidation of services among neighboring hospitals.

The second section of the volume considers the different types of technology which appear to be most crucial in terms of their cost implications. As a prelude to this section, *Rosenthal* differentiates among types of medical technology on the basis of the nature of their future costs and benefits. He presents a typology of medical technologies based on their medical objectives, i.e., diagnosis, survival, illness management, cure, prevention and system management. "To the extent that distinctions can be made among types of technology on the basis of expected costs and benefits, the task of developing policy in this sensitive area might be made more manageable," he states.

Three case studies follow that focus on the nature of the development and diffusion of medical technology. *Rettig* reviews the history of renal dialysis and transplantation and recounts the events, from a political perspective, leading to passage of the Social Security Amendments of 1972. Section 2991 of that law extended Medicare coverage for chronic kidney failure to more than 90 percent of the population. On the basis of this case, he notes that the development of medical technology occurs over a long period of time, is typically international in character, and draws broadly from technical advances in medicine and from developments external to medicine. Thus, he concludes, there is no logical place to intervene in the development process. Commenting on the diffusion of medical technology into clinical practice, he states that "the institutional pathways by which new medical technologies flow into actual use are numerous and diverse. There is thus no centralized institution responsible for the introduction of technology to use."

Willems et al., using the policies associated with the CT scanner as illustrative of government policies regarding the developing and diffusion of medical technologies, note that CT scanners were diffused before their efficacy and safety were assessed. They state that "no systematic assessment has been made of the benefits and circumstances under which CT scanning should be used. No Federal agency has a mandate to require, fund, or conduct large-scale clinical trials meeting high standards of experimental design that could help determine the ultimate position of CT scanning in the practice of medicine." They point to other deficiencies in federal policy that have impacted upon the diffusion and use of CT scanners. These include the absence of clearly defined indications for use that handicaps planning activities, gaps in the Certificate-of-Need laws that allow the regulations to be circumvented by installation of a scanner in a setting not subject to review, and the relatively open-ended federal commitment to finance services, with costs receiving little scrutiny and charges bearing no necessary relation to costs.

Fineberg focuses on current mechanisms that promote the increased use of clinical chemistry tests. He points to factors such as automation, increased insurance coverage, financial incentives to physicians and hospitals, physician training and the practice of defensive medicine as contributing to the rise in use of chemistry tests, often without any change in health status for the patient.

The third section of the book suggests possible policies to control the costs attributed to the use of medical technologies. *Robbins* suggests that it is possible to anticipate the consequences of applied research while it is in its developmental stage. He asserts that such assessments "could provide a more rational basis for certain priority decisions that might serve to inhibit the development and introduction of technologies with unfavorable cost/benefit ratios."

After a survey of the forces within the medical care system that affect the acquisition and use of medical technology, such as the fee-for-service reimbursement system, increased specialization, the use of technology acquisition by hospitals to attract physicians, and the pressure for new treatments and technologies in the face of severely ill patients, *Schroeder and Showstack* review current policies affecting technology use and suggest appropriate responses. The authors note that capital regulations, of which Certificate-of-Need is one example, have not been very effective in the past, but view the National Health Planning and Resources Development Act and its attendant changes as providing the stimulus for a more critical review of proposed new services. Changing reimbursement mechanisms for both physicians and hospitals is seen by the authors as a necessary first step to cost control. They write that if the present incentive system is not altered, "then it seems to us much less likely that any *other* mechanisms devised to allocate resources will be successful." In addition, alternative delivery systems, such as Health Maintenance Organizations, which are constrained to operate under a fixed budget and therefore must perform some rationing of technological services, should be encouraged. The authors also argue for increasing regulatory control over physician supply and specialty distribution; enhancing the Professional Standards Review Organization mechanism by developing, at the national level, a process of technology evaluation and standard setting that would require the National Institutes of Health or other federal agency to issue a social and economic impact statement before funding development of new technology;

and coordinating the reimbursement mechanism with FDA-type regulations governing the market dissemination of new medical devices.

Enthoven and Noll argue extensively against attempts to control costs by imposing economic and technical regulation on providers. Instead, they suggest restructuring the delivery and payment system in a manner that alters the financial incentives facing providers. The basis of their proposal is the creation of competing capitation-financed plans. Financial aid would be based on actuarial categories chosen to capture most of the predictable variation in medical need. Premiums would be determined by individual health benefit plans in a competitive marketplace. For the non-poor a refundable tax credit would replace the present open-ended tax exclusion of employer contributions and the tax deduction of individual premium contributions usable only for premium payments to a qualified health plan. For the poor, Medicaid would be replaced with a voucher system that would be applicable only to qualified plans. Medicare beneficiaries would be permitted to direct that the cost for their actuarial category be paid to a qualified health plan. In all categories, additional benefits could be elected, but would be paid for individually. In addition, the authors propose several regulatory mechanisms that would enhance competition between qualified plans. Specifically, they suggest open enrollment to give everybody a choice among plans; community rating to remove the incentive of plans to seek out preferred risks; establishment of a limit that a family must pay out of pocket in a given year; mandatory information disclosure to assist consumers in selecting alternative plans; and premium setting by market area based on local experience rather than on national experience.

Marks urges the establishment of a federal coordinating agency to analyze the appropriateness and need of the application of new technology. He further asserts that a federal commitment in the form of a stable level of funding is necessary to sustain the biomedical research effort. He maintains that previous short-term agreements with the National Institutes of Health, which reduced support in one year and increased it the next, have "probably led to inefficiencies in the research enterprise and impaired the cost effectiveness of publically supported biomedical research."

Gaus and Cooper suggest five approaches to controlling medical technology. For any of the approaches to be meaningful, however, they urge that an agency be established that would be responsible for evaluating the efficacy and cost-effectiveness of medical technology. Specifically, they propose instituting planning controls such as setting a national limit on capital expenditures controlled through the Certificate-of-Need program or expanding Certificate-of-Need authority to include physicians' offices and clinics and to require recertification of facilities; reimbursement limits such as caps on hospital revenue increases or establishing technology-sensitive fee schedules for physicians; direct market regulation similar to FDA requirements for drugs and medical devices; changes in physician training such as reducing specialization or educating physicians as to the economic consequences of their decisions; and consumer education.

In response to the arguments of Enthoven-Noll and Gaus-Cooper, *Berman and Moloney* examine certain observations in the Enthoven-Noll paper to see why, despite a sharp set of scholastic arguments that regulation cannot work, regulation is in fact continually increasing and broadening. They also explore the consequences presented in the Gaus-Cooper paper to point out potential side effects of various regulatory interventions. Finally, they suggest a strategy to bring the rate of increase in national health care expenditures into line with the overall rate of growth in the economy. The strategy attempts to avoid the side effects of targeted regulatory strategies, noted by Enthoven-Noll and Gaus-Cooper. It aims to leave resource allocation decisions to hospitals and local planning agencies, while providing them with specific recommendations by national scientific advisory committees on how to allocate these resources.

Responding to the Gaus-Cooper paper, *Heyssel* makes the distinction between a general strategy for cost containment and one directed mainly at technology. He dismisses the latter, suggesting that to attempt it would lead to greater problems. Like Enthoven and Noll, he rejects the regulatory approach. Instead he proposes "fundamental changes in the reimbursement of providers, changes in the tax laws to make the consumer aware of the cost implications of the available choices, changes in covered benefits, mandated changes in evaluation of technology, restructuring of the delivery system for capital intensive—high operating cost—technologies, and changes in medical education."

Klarman questions the uncritical use of the frequent statement that one-half of the increase in per-patient-day hospital cost is due to more intensive use of services. After a detailed adjustment of the patient-day cost increase data, Klarman concludes that the increase due to price changes is about two-thirds, and he thus reduces the impact of "intensity" to one-third. Klarman further questions whether anyone can really say anything about the impact of technology from the cost increases due to intensity of services. In the remainder of his paper, Klarman responds to the policy options proposed in the Enthoven-Noll and Gaus-Cooper papers. Like Enthoven-Noll, he dismisses the case for more copayment. While he generally agrees with the arguments set forth by Enthoven-Noll against regulation, he does not view the HMO or other competitive forms of health care delivery as a major policy option.

The last section is a summary of the conference, and presents the major findings and, where possible, suggests a series of options on what type of action the government might take.

It is hoped that the papers will serve as a valuable resource to public sector decision makers responsible for deciding what the government's next moves will be in the battle to control medical care costs.

Acknowledgments

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Perspectives on the growing debate over the cost of medical technologies

Robert J. Blendon and Thomas W. Moloney

To many viewers of American public policy, a national symposium on the effect of medical technologies on health care costs must seem an anomaly. It is well known that the United States devotes more of its resources to scientific research, training, and technological development than do most other industrialized nations. Our substantial space program, explorations of nuclear energy, and major investments in biomedical science do not suggest a nation deeply troubled by the possible economic side effects of continued scientific and technological advancement.

In fact, that advancement has been a major factor in our continuous economic growth. Yet, in the fields of health and medicine, the rapid expansion of technology now has emerged as a major source of public concern. Why has this happened, and particularly in medicine, where improvements in medical care have often resulted directly from new technological advances?

The purpose of this paper is to provide a perspective on the national events leading to the theme of this symposium. In developing this perspective, we will first trace a series of events starting with the Vietnam War and the Great Society, and then examine the evolution of the federal government's efforts to intervene in the medical cost problem.

How the Vietnam War and the Great Society set the stage for the cost control issue

Prior to 1965, most Americans believed that the health sector contained sufficient internal controls so that growth could be self-regulating. It was commonly thought that government should play a very limited role in the medical field, despite the fact that for twenty years health care costs had been rising at rates well ahead of the overall cost of living. The rate of increase was of only minor concern to the American public because the amounts of money actually spent did not preclude the development of other highly desired social programs.

But from 1965 to 1972, there occurred a series of national events that, in the writers' belief, inadvertently propelled the federal government into responding to inflation in the health field with a sense of purpose and a degree of regulatory intervention which could not have been imagined a decade ago. These events, especially the Vietnam War and the Great Society legislation, created inflationary pressures which caused a fundamental change in Americans' perception of the role that government should play in health affairs. The major impetus for the change was the fact that the federal government simultaneously expended $120 billion for a war in Vietnam, enacted a flurry of social legislation which included more than 500 social programs, and implemented a major tax reduction.[1 2 3]

"The critical point with regard to subsequent social policy came in the mid-1960s. At that time, the Johnson Administration quite deliberately avoided asking the country to make a choice between continuing the war in Vietnam and enacting the social programs of the Great Society. Despite the mounting costs of both, restraints were not placed on consumer or public-sector domestic spending, nor on growing military commitments.[4] This conscious policy, in turn, led to a major inflationary spiral. The cost of living increase jumped from one percent a year in 1965 to almost six percent by 1970;[3] the federal deficit rose from $2 billion in 1965 to $23 billion in 1972.[3]

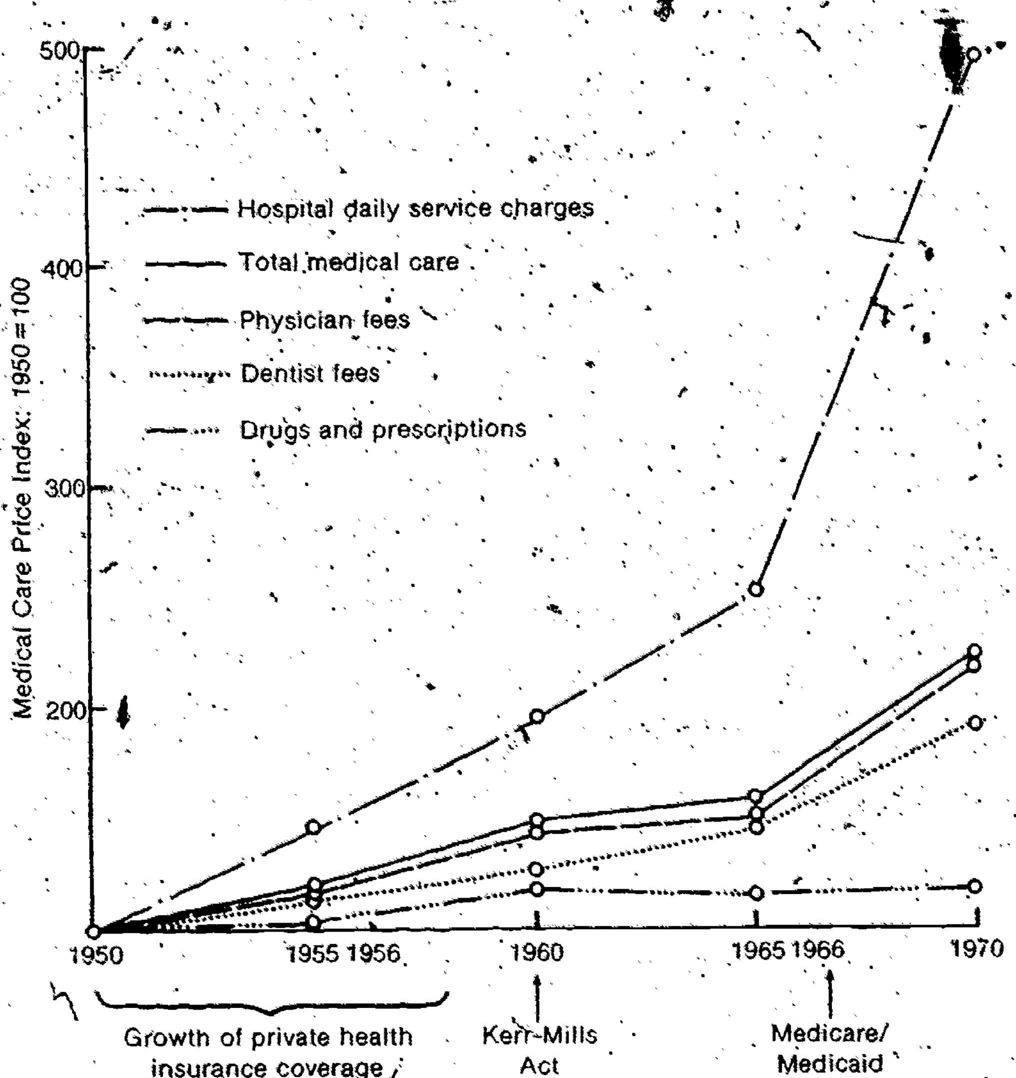
New federal health initiatives played a prominent role in the overall inflationary spiral. The Great Society legislation included two new government programs, one designed to offset medical care for the aged, the other for the poor. The enactment of these two programs marked the beginning of the large-scale growth of American public insurance and the dramatic increase in federal budgetary contributions to the health sector.

Few Americans foresaw that simply changing the way Americans paid for their care would result in a phenomenal growth in the costs of health care. The general belief at the time was that doctors, hospitals, and nursing homes would merely be paid from a different pocket. It was also generally assumed that insurance would have no effect on the way health services were provided. However, once the financial barriers to obtaining care were removed, and individual out-of-pocket cash payments for medical care fell from 53 percent to 38 percent of health expenses, health institutions began to behave quite differently, and an inflationary spiral began.[5] Hospitals in the United States began to build beds at a much faster rate, dramatically upgraded the kinds of service they provided to patients, and markedly increased employees' wages.[6 7 8 9] The resultant increases in costs, strikingly illustrated in Figure 1,[10] were enormous.

They came as a surprise to many Americans, including public officials, distinguished medical leaders, and the American press. For, as shown in Fig. 2, by 1971 national health expenditures (public and private) exceeded the burgeoning expenditures for defense required by our deep, if reluctant, involvement in the Vietnam War.[11 12] As shown in Fig. 3,[13] approximately $39 billion was spent for health care in 1965, but by 1972 national public and private health expenditures had increased to almost $83.5 billion. Concern about this startling rise intensified when it was realized that fully half of the difference between these years—or $22.25 billion—was due to inflationary increases.[13] While not all of them were due to economic pressures within the health field itself (there was a high level of inflation in the economy in general at that time), inflation ran strongest in the health area. As shown in Table 1,[12] the consumer price index rose by about one-third during the period between 1965 and 1972. During the same period, medical

Figure 1

Relative increase in selected components of the Medical Care Price Index 1950–1970[10]



care costs rose by almost 50 percent and hospital charges by a phenomenal 129 percent. Thus, between 1965 and 1972, health expenditures grew from 2 to 8 percent of the federal budget.[12]

These huge and inflationary health expenditures caused a number of reactions. They became a major target for political leaders who wished to institute counterinflationary methods and began to pose a serious threat to the enactment of other socially desirable programs. Furthermore, they put in serious question the recurring issue of a future national health insurance program. For years, many Americans had been attempting to bring the United States system of insurance coverage up to the standards of Canada and Western Europe. These countries had developed insurance systems which provided protection for 98 percent of their citizens and covered almost 90 percent of the costs of providing health care services.

Figure 2

National health expenditures vs. national defense expenditures 1960–1973[11 12]

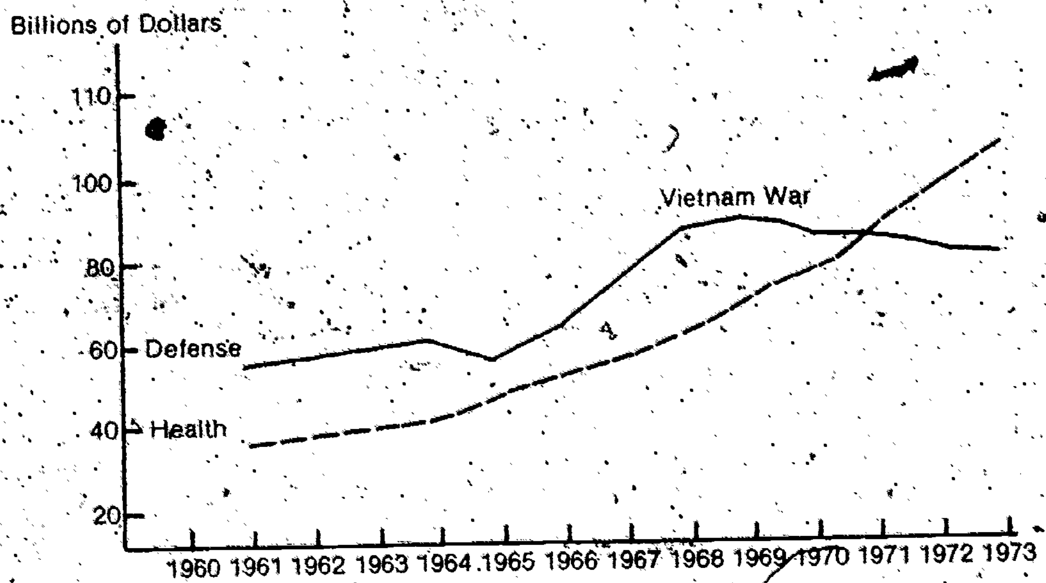
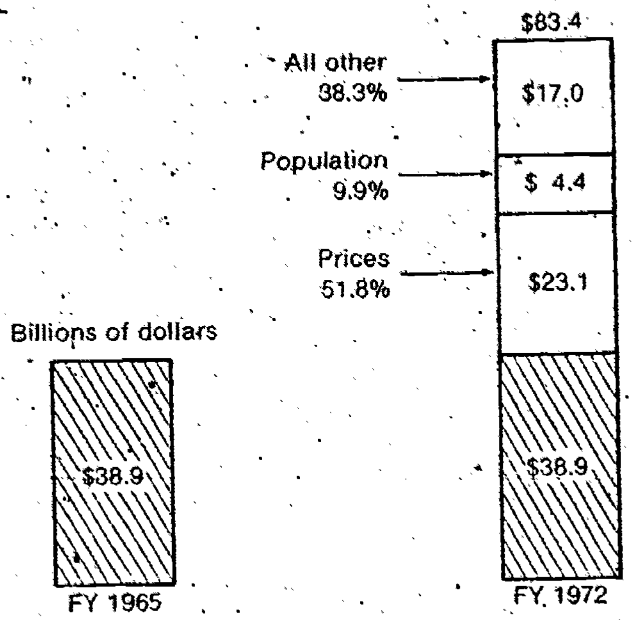


Figure 3

National health expenditures[13]



In contrast, public and private insurance in the United States provides coverage for about 90 percent of the population, and many individual citizens remain responsible for a third of the costs of the care that they receive.[14 15 16] As a result, many Americans find our system of insurance coverage inadequate; as an example, they point to the financial disaster encountered by families unfortunate enough to have one member develop

Table 1
Rate of Increase in Consumer Price Index[12]
1965–1972

Items	*Increase rate*
1. All items	33%
2. Food	31
3. Transportation	25
4. Medical care	48
5. Hospital charges (semiprivate room)	129

a catastrophic illness.[16] In addition, only minimal insurance is available to cover the costs of outpatient medical services.[17] This creates additional financial hardships and often causes individuals to delay getting needed medical care, thus increasing their chances of becoming seriously ill.

It was apparent by 1972 that the national desire for better health insurance could not be addressed unless escalating health care costs could be controlled. For example, if the inflationary portion of the increase in expenditures between 1965 and 1972—$22.25 billion—had been kept at half of that actually experienced, then the United States could have used the other half to enact, in 1977, a national health insurance program similar to those of Western European countries.[13 14 18] But the unique brand of inflation permeating our economy in the 1970s has made this decade a particularly difficult one in which to introduce major social legislation such as a national health insurance program. This form of inflation, termed "demand-pull inflation," characterized by the simultaneous rise in both unemployment and inflation, has defied our standard economic attempts to bring it under control. It has left both our national political leadership and our economic experts with an unusual sense of uncertainty about the future performance of our economy and, therefore, a reluctance to introduce expensive new social programs.[19]

The nation faces three other constraints to expanding our health financing programs. First, even without a national health insurance program the United States already has a relatively high-cost health care system (Table 2).[20 21 22] Second, during the last decade we have experienced one of the Western World's lowest rates of real economic growth, so that new dollars are unavailable for such a venture (see Table 3).[23] Third, of all Western countries we continue to devote the largest share of our economy to defense spending, so that it is more difficult to find resources that might be devoted to health and medical matters (Table 4).[5]

The forces motivating expenditures for social programs or for defense are quite different. Defense expenditures have been made in response to our national desire to maintain the ability to deter either conventional or nuclear attack. We maintain this ability on behalf of Canada and a number of allied Western European and Asian countries as well as on our own. This commitment to the defense of other nations has led the United States to spend a larger share of its economy on defense than do most Western

Table 2
Total health expenditures as a percentage of the Gross National Product, 1970[20 21 22]

	Health expenditures as a percentage of GNP
United States	7.2%
Canada	6.7
Sweden	8.3
United Kindgom	5.4
Norway	6.5

Table 3
Average annual rate of growth in per capita GNP (1965 dollars), 1965 to 1975[23]

Country	*Growth rate 1965–1975*
United States	1.1%
Denmark	2.5
West Germany	7.9
Netherlands	3.1
United Kingdom	–.2
Norway	3.8
Sweden	3.2
Canada	4.0

Table 4
Military expenditures as a percentage of GNP, 1974[3]

Country	*Percentage*
United States	6.2%
Denmark	2.4
West Germany	3.6
Netherlands	3.5
United Kingdom	5.2
Norway	3.1
Sweden	3.1
Canada	2.1
U.S.S.R.	more than 10

countries; in fact, in recent years the United States' defense expenditures have been very similar in size to those of the Soviet Union. Expenditures for social programs, on the other hand, have been made in response to domestic political pressures rather than to the potential threat of international events.[19 24]

Although there is not, in theory, a direct relationship between these different types of expenditure, our actual history in the post-Korean War period suggests that: (1) there has been very little growth in the share of the Gross National Product devoted to federal expenditures, and (2) within this self-imposed ceiling, the size of the defense budget has at least indirectly affected the amount of funds available for domestic social programs. Overall federal expenditures have risen only about one percentage point every four and a half years—from 18 percent of the GNP in 1955 to 23 percent in 1977.[25]

Simultaneously, a decrease in national defense expenditures has been accompanied by an increase in expenditures for domestic social programs: defense expenditures have dropped from 9.3 percent to 5.8 percent of the GNP from 1960 to 1976, while expenditures for domestic social programs have increased from 5.8 percent to 12.5 percent.[3]

In order for the United States to expand its health financing system to a significant degree, experts believe it will have to remove at least one of four enormous obstacles. We must either: (1) reduce the cost of the current health care system, (2) substantially improve the country's real economic growth, (3) significantly reduce spending for national defense, or (4) reduce expenditures for other social programs (welfare, housing, etc.). In the minds of many, solution (1) seems to be the most feasible. Given the slowness of the country's economic recovery, the intransigence of the Soviet Union in arms limitation talks, and the pressures for other social areas, that solution seems the only real alternative; reducing the relative cost of the current health care system may well be the essential step toward realizing a longstanding hope—the enactment of national health insurance.

Thus, the impetus exists for serious governmental efforts to control medical care costs. However, unless we trace the evolution of these efforts, it is difficult to imagine how they have come to focus specifically on the issue of controlling medical technologies.

Earlier governmental efforts at cost control

By 1968, it had become clear that improved public and private health insurance coverage, while greatly increasing the financial security of individual citizens, had also generated a wave of inflation in the health field. As a result, a number of academic economists and political conservatives called for a reduction in the scope of public and private insurance. They argued that control of inflation required less, not more, health insurance coverage.[26,27] Although their arguments were considered technically sound, this approach was not politically viable. Americans were not considered willing to return to personal payment of large and unpredictable medical bills as the price of slowing inflation in the health sector.

In the search for a workable solution, the federal government's first choice was to call for voluntary, self-imposed restraints. These efforts included slight adjustments in the design of private and public health insurance payment systems. In addition, prominent individuals serving in private agencies were asked to define and plan on a voluntary basis for their communities' health needs.[28,29] These voluntary efforts were largely ineffective; the inflationary pressures were so great that private planning bodies were unable to make the kinds of decisions required to curtail the rapid inflationary spiral.

A second effort was aimed at improving the management of the nation's hospitals. It was reasoned that if hospitals had a "managerial revolution," and thereby reduced their inefficiencies and improved their apparently low levels of productivity, inflation might be brought under control.[30,31] Thus, the United States invested heavily in programs to improve the quality of continuing education programs for hospital administrators. At the same time, hospitals began to implement advanced management techniques.[32] A curious result of this effort was that expenditures grew at an even faster rate as better trained management teams entered the hospital sector. Some have speculated that this might be because better management made hospitals more adept at attracting resources to improve the quality of their individual institutions. In any case, the result was in sharp contrast to the expectation that overall expenditures would be reduced.

With the apparent failure of these two efforts, many Americans began to move away from their traditional assumption that the health sector could be self-regulating and toward the belief that there was a need for more government involvement and regulation. Here, however, the exact nature of the mandate was unclear. Many people had serious misgivings about the usefulness of a stepped-up federal role and/or little trust in the ability of the government to administer effectively any interventions which on the surface might be appealing. However, the general feeling eventually prevailed that the government had to do something more.

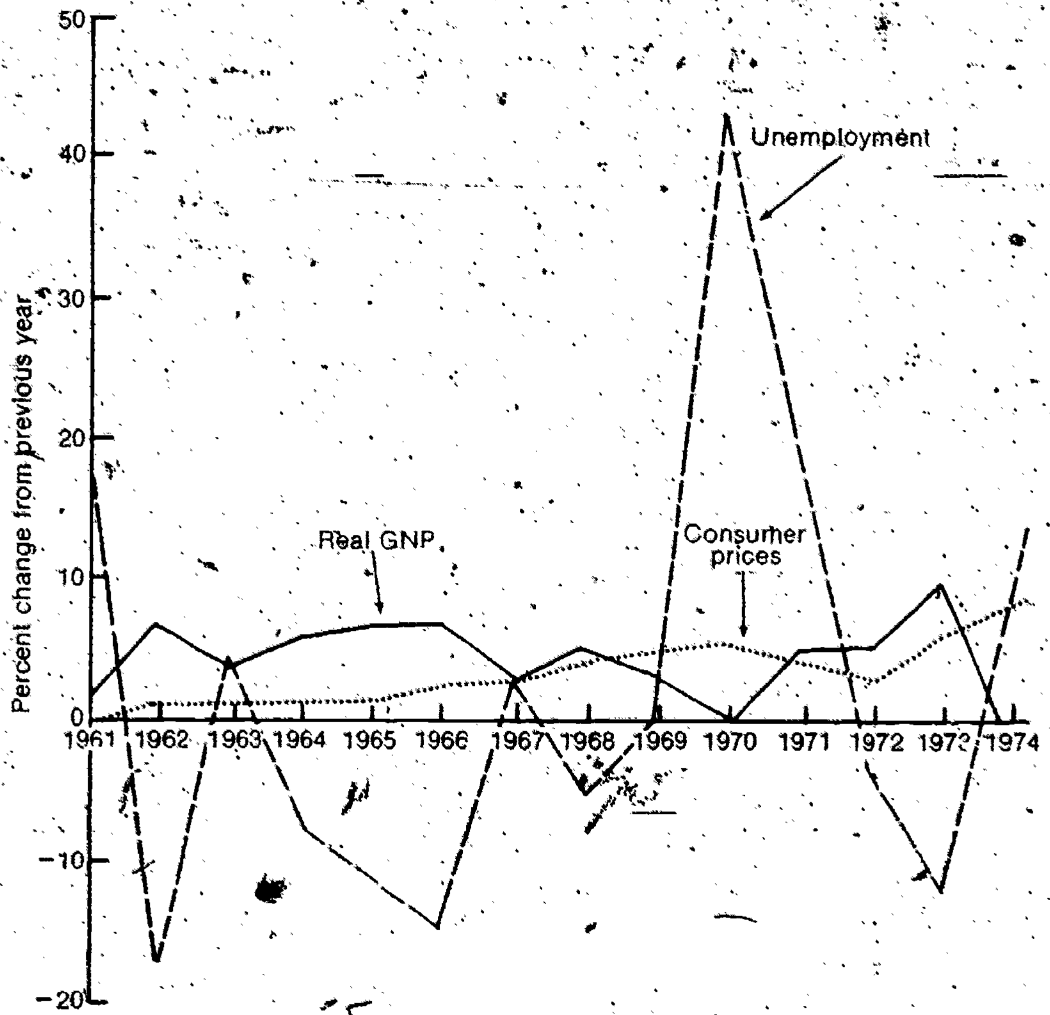
As a result, the United States developed a series of interventionist mechanisms by which the government, without taking over the ownership and operation of the major health institutions, started to play a major regulatory role in the provision of medical care. It instituted (1) limits on the proliferation of costly capital equipment and facilities, and (2) limits on the rates of hospitalization. Limiting capital expenditures was a form of regulation termed "franchising." Prior to this time, hospitals had independently decided whether they wished to construct new facilities or clinics. As a result of franchising, an external public agency now would be empowered to decide whether new capital facilities could be constructed in a given geographical area.[29, 33] Limiting rates of hospitalization, the second control device, was a form of regulation termed "utilization control." This form of intervention was developed in response to the growing belief that current forms of health insurance encouraged expensive overhospitalization.[34] External bodies now would supervise who should use the hospital and which services the hospital would provide. The hope was to reduce the country's hospitalization rates to a point where they would be more comparable to those found in Western Europe and in health maintenance organizations in the United States.

Neither of these two types of regulation proved able to limit substantially either the rate of growth in health care expenditures or the health care component of the Consumer Price Index. Health expenditures continued to increase faster than other segments of the economy. Meanwhile, the general national economic outlook remained bleak.

In 1970, a new administration attempted to slow these inflationary forces in the overall economy by using a combination of conventional economic tools of restrictive monetary policies and federal budget austerity. However, as can be seen in Fig. 4, the results of this policy were again not what we had hoped to achieve. Not only was the country left with high levels of

Figure 4

The changing state of the economy: 1961-1974[1]



inflation, but the unemployment rate suddenly jumped to levels higher than any since the Great Depression.[1]

This alarming situation created a further shift in public attitudes toward the federal government's taking a direct role in the management of the total economy. In response, the Nixon Administration undertook wage and price controls. This was the first time such a drastic measure had ever been employed in peacetime. The action gave the federal government unprecedented authority to intervene in the health care economy. Only such a crisis and such a program could have led to a policy that allowed an external body to determine the prices that could be charged by private hospitals and physicians.

The results of this particular intervention were dramatic. As shown in Table 5, for the first time in a quarter of a century hospital and medical care rates of price increase fell below those for the overall cost of living. In the years between the enactment of the Medicare and Medicaid programs and the beginning in 1971 of the Economic Stabilization Program, the

Table 5
Average annualized price increases (Consumer Price Index)[34]

Period	Overall cost of living	Total medical care component	Semi-private hospital room charge
1950–1955	2.2%	3.8%	6.9%
1955–1960	2.0	4.1	6.3
1960–1965	1.3	2.5	5.8
Pre-Medicare (FY 1963–66)	1.7	2.4	5.4
Post-Medicare (FY 1966–69)	3.7	6.5	15.6
Pre-Economic Stabilization Program	5.6	6.7	13.0
Economic Stabilization Program (1971–74)	6.6	4.3	5.6
Post-Economic Stabilization Program (1975)	11.2	14.5	21.7
1976	4.8	10.7	11.7

Consumer Price Index for semiprivate hospital room charges increased at an average of 14.3 percent per year. During the Economic Stabilization Program years, the increase dropped to an average of 5.6 percent a year.[35] Of all the interventions attempted, this program has to date been the only one since the enactment of Medicare and Medicaid that significantly changed the rate of expenditures for health care in the United States.[36 37 38]

By the end of 1974, the general economy had begun to improve; and, as promised, the Economic Stabilization Program came to an end. As a result, federal limitations on the prices that hospitals and physicians could charge were lifted. When this happened, medical care prices jumped ~~right back~~ up. They now continue to rise at a rate similar to that before the Economic Stabilization Program—1½ times as fast as the overall cost of living.[35]

Future federal initiatives

We now have a new administration in Washington which has indicated that national health insurance still remains a major priority. Clearly, if this is to be the case, other forms of governmental intervention to control costs of medical care will be examined. Given the forms of regulation already in place, there appear to be only four other types of intervention open to the government at this time: (1) regulate the prices that hospitals and physicians can charge, (2) limit wages paid to health professionals and ancillary personnel, (3) limit the numbers of workers employed by health institutions, and (4) limit the proliferation of new medical technologies.

The first three of these alternatives all respond to the fact that rising costs are closely associated with the unusual labor intensity of the health sector.[39] The Administration has already unsuccessfully proposed legislation limiting the rate of increase in prices hospitals could charge. The second alternative comes into direct conflict with the bitter feelings that emerged during the Economic Stabilization Program, arising from what was considered to be the unfairness of wage controls determined by a distant government in Washington. The third option seems difficult to suggest at a time of high unemployment, particularly since health institutions are such large employers of women, minorities, and unskilled workers.

The lack of appeal of the first three options has led to the current serious consideration of the fourth, evidenced by (1) the attention given by the media to the costliness of the new wave of medical technologies, most recently the computerized axial tomography (CAT or CT) scanners; (2) the number of professional conferences and committees exploring the possibly negative role of medical technology; and (3) the considerable recent efforts within various legislative branches to stem the tide of the introduction of new hospital-based technologies by designing programs for more ambulatory care.

Concern about the possible adverse effects of medical technology in general has become a regular part of public dialogue. Most importantly, and perhaps for the first time in this country, various groups are suggesting slowing or even temporarily halting the introduction of new medical technologies. Of particular interest has been the suggestion that perhaps expensive new clinical services or devices should be subject, prior to their introduction, to some mechanism for public approval based on demonstrated effectiveness and cost impact.[40] This proposal is analogous to the current constraints placed by the Food and Drug Administration on the introduction of new drugs.

Conclusion

Thus, the events of the last decade have set the stage for the discussions at this conference. Because of the pressure to add national health insurance to the country's pending legislative agenda, additional governmental efforts to control health care costs are likely to be given serious consideration by the new administration and the Congress during the next few years; and there is a danger that the political pressures may be so powerful as to push aside the necessary and complex task of examining the actual relationship between health care costs and medical technologies.

In prior times, the increased costs associated with scientific progress were considered the necessary price of improvements in medical care. To change this policy could have long-term consequences for our future medical treatment capabilities. Before public action is taken, it is essential, first, to determine what costs are imposed on the health sector by the introduction of new technologies, and, second, to make a careful assessment of the actual need, the feasibility, and the possible long-term consequences of proposed governmental controls on the introduction and use of new medical technologies.

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Is medical technology the culprit behind rising health costs? The case for and against

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Stanley S. Wallack

In September 1975, Clifton Gaus, representing the Social Security Administration (Medicare), concluded that

> adopting new health care technology is a major cause of the large yearly increases in national health expenditures. . . .[1]

One year later (October 1976), Selma Mushkin and her coworkers reported that

> we find at least for the period 1930-75 that biomedical research on balance reduces health outlays rather than inceases [them].[2]

The methods by which these two analysts arrived at such opposite conclusions is of interest itself. But the question of critical policy significance is which one is true. Clearly, if technology decreases health expenditures, there is no need to discuss control of the adoption and diffusion of expensive medical technologies. If one accepts Gaus's conclusion, however, one need not infer that innovative medical technologies must be controlled, but it is a necessary first condition for their adoption.

Because this is only one of 16 papers that will grapple with the issue of technology and health costs, many aspects of this problem will be left to others. This paper is deliberately lacking in balance. We will concern ourselves entirely with the expenditure side of the equation, leaving to others the assessment of the value of specific technological procedures. This paper will attempt to assess whether or not technology has led to more or less spending for health care. So as not to create a false sense of anticipation, we will state at the outset that it is not possible to support either conclusion with certainty. But there is sufficient evidence against technology to bring it to trial to determine if it is indeed "the culprit behind rising health costs."

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Framework for discussing technology

Our interest is not in technology per se, but in how technology has affected the growth in health expenditures. Health expenditures rose from 5.9 to 8.6 percent of the Gross National Product between 1965 and 1976. This increase is attributable to population growth, price increases, and higher per capita utilization of medical services. Over 50 percent of the increases resulted from higher prices, and over one-third from per capita increases in the quantity and quality of health service utilized. Institutional and outpatient care both increased, but institutional care grew at a much faster rate. Expenditures for hospital and nursing home care as a proportion of all health expenditures rose from 37 to 47 percent during the same 11-year period.* Hospital expenditures have received the bulk of attention because they account for 40 percent of total health expenditures.

The increases in prices and utilization reflect the significant changes in the demand and supply. Higher per capita incomes can be expected to generate greater demands for health care, but the extensive growth of private and public health insurance seems an even more important factor. Third-party payments covered about one-quarter of expenditures in 1950; by 1976 this figure approached 70 percent. When individuals are not paying the bill directly, their sensitivity to prices and price increases diminishes. A 1000 percent increase in hospital costs since 1950 without a noticeable change in out-of-pocket payments has occurred because of the growth of private and public health insurance. The demand for health care was met by an expansion of the delivery system. The numbers of both hospital beds and personnel have grown steadily, by over 50 percent since 1960.

Extensive insurance coverage and uncertainty about the benefits from health care provide incentives that lead to the use of services of low or of no marginal value. Technological advances, which increase the number of tests and procedures capable of being performed, create the potential for providing even more services of low marginal value. However, technology need not always add to the cost of treatment; it can also reduce the cost of care or the amount of care needed to treat specific diseases. When it appears that costs will increase because the technological advance itself is expensive, questions as to its effectiveness and efficacy are apt to be raised. The constant questioning, which is becoming a common occurrence, emanates from a growing concern that the large increases in medical expenditures over the past 10 to 15 years have not produced a corresponding improvement in health status as measured by improvements in survival rates for the most prevalent diseases.

In evaluating the impact of technology it is important, therefore, to differentiate between those technological changes that are associated with providing a given treatment more efficiently and those technological advances that encourage the use of additional treatments. Some technologies affect only one dimension, others have a combined effect. These

* For a review of recent trends in total and public health expenditures see Congressional Budget Office, *Expenditures for Health Care: Federal Programs and Their Effects*, August 1977.

latter types are the more difficult ones to manage if a control policy is adopted. For example, the auto-analyzer substantially reduces the cost per laboratory test, but facilitates the ordering of many more tests. Analyzing changes in total expenditures for laboratory tests only, combines the two effects. To the extent that future policy decisions are based on limiting the availability of cost-raising technologies, the adoption of auto-analyzer-type equipment might be incorrectly impeded. Instead, a policy should be sought that encourages the adoption of per-unit cost-reducing equipment, but discourages questionable increases in utilization.

Figure 1 shows a sample matrix that separates these effects. Technological advances, such as immunization against polio, which reduce the cost of treatment and incidence of the illness obviously reduce costs (lower right box). Conversely, hemodialysis units and other therapeutic advances which increase both per-unit treatment costs and utilization of services will raise total health expenditures (upper left box). Diagnostic treatments, such as CT scanners and automated clinical laboratories, which raise and lower per unit costs respectively, will raise or lower total health expenditures depending upon how extensively they are utilized. Thus, in two of the four boxes, question marks seem appropriate.

A clear definition of the term "technology" should precede any attempt to measure its impact on health spending. Yet, few of the studies discussed in this paper develop such a definition, and even when they do, such a definition is irrelevant to the statistical analysis employed. Each of four techniques used thus far to measure the impact of technology has usually circumvented the lack of precise definitions by employing crude proxy measures. The *residual approach* method measures the impact of all other relevant variables on changes in health-care spending and then defines the residual (either positive or negative) as the effect of technology. The excess inflation approach (used mainly for hospital spending) separates out those expenditure increases due to general inflation and those due to excess or above-average hospital employee wage increases, and defines what remains as the growth in the quality and quantity of services, a significant portion of which is thought to be technologically induced. The *specific illness approach* analyzes changes in the overall cost of treating specific illnesses or medical conditions over time and then attempts to explain what occurred, using detailed knowledge of changes in the procedures employed. Finally,

Figure 1
Impact of a technical advance on health care expenditures

Average cost per unit		Utilization	
		Higher	Lower
	Higher	+	?
	Lower	?	

the *specific technique approach* avoids the problem by focusing on one procedure or technique and tracing its impact over time.

The researchers who have used these proxy approaches are not to be faulted for their lack of precision. The problem rests with the lack of sufficiently detailed statistical information, which inhibits the conversion of precise definitions into meaningful measurement techniques. In this paper we will not attempt to add to the confusion by presenting a definition of our own. Rather, we will explain at least some of the seeming differences in results as due to either definitional differences or lack of comparability in the units of measurement employed.

At least initially, the definition of technology should be interpreted broadly rather than narrowly. Often when technological advances and their associated costs are discussed, prevailing diagnostic and therapeutic equipment and procedures become the focus. Accepting this limited definition excludes some very valuable additions to the health care providers' armament, advances which have achieved significant cost savings by decreasing the need for expensive treatment, particularly hospitalization. The best examples of such technologies are immunizations and drug therapies for infectious diseases, such as tuberculosis, lobar pneumonia, diphtheria, poliomyelitis and mental illness. It is also important, where possible, to adopt a broad definition of health expenditures. Concentration on hospital costs only can miss those technologies that have eliminated the need for hospitalization.

The case against technology

The major studies that have shown technology to increase costs have concentrated on the hospital sector only. As noted above, this could be a serious limitation to the extent that analysis of hospital costs alone, particularly per diem costs, excludes those technological benefits that avert the need for such care. Nevertheless, since hospitals account for 40 percent of health expenditures, they are the major cost center in the medical sector. Hospitals are also the arena where most new technologies are employed.

The Gaus (Social Security Administration, or SSA) conclusion that new health care technology is a major cause of rising medical expenditures builds on findings made during the design of the Economic Stabilization Program health cost control plan using the excess inflation approach. An SSA analysis indicated that only about 50 percent of the total increase in the cost per hospital patient day between 1965 and 1971 could be accounted for by general inflationary trends in the economy,[34] that is, by higher wages paid to hospital employees or prices paid by hospitals for their supplies. The other 50 percent came for "other things" or represented increases in goods and services per patient day. As can be seen in Table 1, where the term "Changes in Services" captures "other things," there have been increases in both labor and nonlabor inputs. In the period 1967–71, the cost of a day of hospital care went up at an annual rate of 14.0 percent. Of that amount, 7.8 percent was due to general inflation, leaving 6.2 percent to be

Table 1[8,9,7]

Sources of increase in hospital cost per patient day, selected fiscal years

Item	Average annual percent increase						
	1960–65[a]	1965–67	1967–71	1971–73	1974	1975	1976
Total increase	6.7%	10.4%	14.0%	10.5%	9.8%	15.8%	14.7%
Increases in wages and prices	3.4	3.9	7.8	5.2	6.8	10.7	8.3
Wages	4.7	4.8	9.9	6.3	5.2	9.8	9.0
Prices	1.3	2.6	4.8	3.8	9.0	11.0	7.1
Changes in services	3.3	6.5	6.2	5.3	3.0	5.1	6.4
Labor	1.7	3.9	2.9	2.3	0.7	2.7	2.2
Other (non-labor, e.g., x-rays, lab tests, etc.)	5.9	10.5	11.0	9.3	6.0	7.5	10.6
Percent of total increase due to:							
Wages and prices	50.7	37.5	55.7	49.5	69.4	67.7	56.3
Services	49.3	62.5	44.3	50.5	30.6	32.3	43.7

Source: Price data are from the Consumer Price Index, Bureau of Labor Statistics. All other data are from *Hospitals, Guide Issue*, August 1, various years and *Hospital Statistics 1973*, American Hospital Association 1974. Data for fiscal years 1973–76 are from the Hospital Panel Indicators Survey.

[a]Figures calculated on a per patient day basis; figures for all other periods are calculated on a per adjusted patient day basis.

explained by the addition of new employees, the purchase of more and better medical equipment, or just more administrative costs.

Whereas, about 2.25 hospital workers were employed per patient day of care in 1960, the rate exceeded 3.5 by 1975. The growth in nonlabor inputs has been even more dramatic, with the annual increase doubling from about five percent in the early 1950s to over 10 percent by the late 1960s. These nonlabor inputs include the cost of new billing equipment needed to fill out forms required by government and the costs of additional diagnostic tests, as well as the costs of remodeling an old hospital wing or an entire new building. Also included as nonlabor inputs are the acquisition of new technological innovations and existing innovations put in place by other hospitals.

In a recent study on hospital costs prepared for the Council on Price and Wage Stability, Martin Feldstein and Amy Taylor came to a similar conclusion as the SSA analysis for the 20-year period 1955–75.[10] For this period, the average cost per patient day (ACPPD) in 1967 dollars rose at an annual rate of 6.1 percent. They estimated that only one-fourth of the increase in the cost per hospital day in excess of the general inflation level was the result of higher wages paid by hospitals; or that 75 percent of the relative increase could be attributed to the increase in real inputs per patient day. That is, if hospital employees' earnings had increased in line with all private nonfarm workers, the annual increase would have been 5.0 percent (Table 2). Hence, the Feldstein and Taylor study supports the basic conclusion of Gaus and the SSA that the hospitals of today are using far more inputs, more technology, and more employees, to produce an increasingly sophisticated style of hospital care, and that this has added appreciably to the cost of hospital care.

Table 2

Annual rates of change in earnings and labor costs[10]

	Earnings of hospital employees (1)	Earnings of all private nonfarm employees (2)	ACPPD[a] (3)	ACPPD[a] if hospital employee earnings increased like all private nonfarm earnings (4)	ACPPD[a] in 1967 dollars (5)	ACPPD[a] in 1967 dollars if hospital employee earnings increased like all private nonfarm earnings (6)
	Annual percentage rates of change of					
1955–60	4.8	3.6	6.9	6.2	4.7	4.0
1960–63	3.9	3.1	6.5	6.0	5.3	4.8
1963–66	4.0	3.8	7.4	7.3	5.3	5.2
1966–69	9.5	5.1	13.3	10.6	8.8	6.1
1969–70	10.1	4.2	15.7	12.2	9.2	5.7
1970–71	10.3	6.5	13.9	11.7	9.2	7.0
1971–72	8.1	7.0	14.0	13.5	10.3	9.8
1972–73	4.6	6.8	9.0	10.2	2.6	3.8
1973–74	5.6	6.2	11.6	12.0	0.6	0.2
1974–75	10.8	6.1	18.3	15.7	8.4	5.8
1955–66	4.4	3.5	6.9	6.3	5.1[b]	4.5[b]
1966–75	8.7	5.8	13.6	11.8	7.4	5.6
1955–75	6.3	4.5	9.9	8.8	6.1[b]	5.0[b]

Source: Martin Feldstein and Amy Taylor, "The Rapid Rise of Hospital Costs," Discussion Paper No. 531 (Jan. 1977), Harvard Institute of Economic Research, Harvard University, Cambridge, Mass., Table 5, p. 17.

[a]ACPPD: Annual cost per patient day.

[b]These numbers have been recalculated from the original article.

This level of analysis has certain limitations. First, we cannot estimate with any precision what proportion of the increases in labor and nonlabor costs can be attributed to technological changes and diffusion, nor do we know very much about the composition of the nonlabor components. Are the technological increases mostly small items, such as tests and procedures, or are they major purchases, such as open heart surgical units and intensive care facilities?

Such an approach has been criticized by Paul Gertman, who argued that concentrating on only changes in the cost of a day of hospital care omitted several important factors that could turn the equation in favor of technological innovations as a "net" cost saving factor.[11] These other factors include declining length of stay per hospital admission, the costs "averted" by eliminating hospitalization for patients who prior to the introduction of a particular drug or procedure would have required it, and the changing composition of the United States population.

While the German criticism cannot be dismissed, an analysis of aggregate statistics casts doubt on his positive assessment of the impact of technology.* Although the average length of a hospital stay has decreased from the 1968 high of 8.4 days to its current level of 7.8 days, this level is still .2 of a day higher than it was in 1960 (Table 3).

Using the Feldstein/Taylor constant dollar estimate of average "real" (i.e., 1967 dollars) cost per patient day, the cost per hospital stay was calculated for 1960 and 1973. As shown in line 5 of Table 3, the per-stay "real" cost in 1973 was more than 2.4 times the cost of a stay in 1960. But the potential trade-off between increased capitalization and shorter lengths of stay is important to keep in mind. In fact, this is one key reason that the unit of control used in both the Economic Stabilization Program's Phase IV control system and the suggested hospital cost containment proposal of President Carter is expenditures per hospital admission rather than spending per hospital day.

With respect to the issue of "averted" costs, there is also reason to question German's optimism. Certainly there have been technological breakthroughs which have drastically reduced the need for hospitalization for particular diseases. But have they been sufficient to overcome the extra cost of treating unresponsive illnesses or the costs of new attempts to cure previously incurable, fast-mortality costs? On a quick and unsophisticated level (a discussion of more sophisticated analyses of aggregate health care spending in later sections), if the *net* impact had been positive, *per capita* "real" spending per hospital admission would have declined. But as shown in Table 3, line 9, such spending actually went up faster than per-admission costs (2.9 times versus 2.4). This is a result of hospital admissions

*In later discussions, German emphasized that his comments about the positive impact of technology are probably more appropriate with respect to explaining changes in total health expenditures than in hospital spending only.

Table 3[5,10,12]

Various estimates of hospital costs

	1960	1973
(1) Average cost per patient day, current dollars	$32.23	$114.69
(2) Consumer Price Index (1967 = 100)	0.887	1.331
(3) Average cost per patient day, (real) 1967 dollars	$36.34	$86.17
(4) Average length of a hospital stay (days)	7.6	7.8
(5) Estimated average (real) cost per hospital stay [(3) × (4)]	$276.18	$672.13
(6) Hospital admissions	23.0 mil	31.8 mil
(7) Total (real) hospital expenditures [(5) × (6)]	$6.4 bil	$21.4 bil
(8) U.S. population	180 mil	210 mil
(9) Per capita estimated real cost per hospital stay [(7) ÷ (8)]	$35.00	$101.90
(10) Percentage of population under 5 or over 65	22.8%	19.8%

Source: Estimates derived from *American Hospital Association Guide to the Health Care Field*, 1975 Edition, American Hospital Association, Chicago, 1975, Table 1, pp. 17-18. (Total Nonfederal Short-term General Hospitals and Other Special); *Health*, United States 1975, DHEW National Center for Health Statistics 1976; Martin Feldstein and Amy Taylor, "The Rapid Rise of Hospital Costs," *Harvard Institute of Economic Research Series* (Cambridge, Mass.), 1977.

rising faster than the population (38 percent versus 16 percent). Finally, it appears that the marginal impact of the changing composition of the United States population between 1960 and 1973 should have been to lower, not raise, hospital expenditures. In other words, on an age-adjusted basis, hospital expenditures actually have gone up faster since 1960 than it revealed in the simple aggregate statistics. In 1960, the percentage of the population most vulnerable to hospitalization—under five years of age or over 65—was 22.8 percent; by 1973 it had declined to 19.8 percent.

The positive findings of the excess inflation approach also have been supported by a multivariate regression analysis by Karen Davis. Davis used a time trend variable *(residual approach)* to depict the impact of technology on hospital costs, after adjusting for changes in demand, case mix, and usage rate. She found technology to account for about 25 percent of the annual increase in hospital expenses per admission for 200 hospitals during the years 1962–68.[13] The importance placed on technology is consistent with the excess inflation approach, which would attribute to technology a substantial portion of the increase in per diem hospital costs due to changes in labor and nonlabor inputs.

An important component of the rise in per diem hospital cost has been the spread of modern technologies from medical centers to smaller and smaller community hospitals. In a study of the diffusion of new hospital technologies, Louise Russell has systematically analyzed this process since the end of World War II.[14] She estimated that the rapid diffusion of just one technological innovation, intensive care units (ICUs), could account for almost 10 percent of the cost of an average hospital day in 1974. What is of particular concern to Russell is that this rapid diffusion took place without a thorough analysis of the benefits of such treatment. In fact, recent studies seem to suggest that the routine use of ICUs is harmful to some patients.[14]

In summary, the consistency of the hospital cost findings reported above, the spread of complex technologies to more hospitals, and the development and deployment of expensive diagnostic and therapeutic equipment leave little doubt that the cost of a day or a stay in a hospital has risen significantly in the past 15 years because of technological advances and diffusion. But this is only part of the answer; it is only the visible effect of technology. The technologies that reduce the need for hospitalization or shorten the length of stay are invisible to such an approach. Our attempts to measure these invisible effects have thus far been preliminary. Thus we cannot yet declare technology guilty.

Impact of technological change on selected illness

Unfortunately, there has been very little analysis done on the cost of treating particular conditions. The most extensive work has been done by Anne Scitovsky and Nelda McCall on patients treated at the Palo Alto Medical Clinic for the 1951–71 period. They analyzed eleven conditions commonly found in hospitals, including appendicitis, maternity care, pneumonia, and forearm fractures.[15 16] They found mixed results: real costs declined for five of the eleven conditions studied.

In general, the cost savings found were largely the result of shorter lengths of hospital stay. For example, in the case of maternity care, the average length of stay decreased from 4.6 days in 1951 to 2.8 days in 1971. The cost-raising impact of technologies often occurred because more diagnostic tests and therapeutic procedures were performed. For example, the average number of diagnostic tests for a perforated appendix rose from 5.3 per case in 1951 to 31.0 in 1971.

For the eleven conditions, cost-raising aspects of technological changes exceeded the cost-saving ones. In fact, the real cost increase for treating one condition, myocardial infarction, far outweighed the combined cost savings of the five conditions for which real costs decreased. The increased use of intensive care units was largely responsible for the much greater treatment cost for myocardial infarction, but a significant increase in the number of tests and procedures also occurred. For example, the number of inhalation therapy treatments rose from 12.8 in 1964 to 37.5 in 1971.

Of the various approaches used to analyze the impact of technology, the specific-illness approach is by far the most detailed. It does have a number of drawbacks, however. First, technological improvements may affect the incidence of various illnesses. If through technological advances some illnesses are prevented or cured, treatment of patients with other diseases will of necessity increase, and they could be more expensive to treat. Another measurement problem with the approach is that through technological advances, illnesses not previously treatable (not necessarily curable) become amenable to treatment. Finally, an illness-by-illness approach to determine the impact of technology on health expenditures is a cumbersome and expensive investigatory process. The Scitovsky-McCall study, for example, needs to be corroborated by similar analyses in other settings. Of particular interest is whether it is a few conditions, such as the care of myocardial infarctions, that are generating the much greater increases in total hospital costs, or whether the substantial cost increases are attributable to many conditions. Finally, the Scitovsky-McCall findings are limited by the small number of conditions analyzed; an illness-based study on the ten most prevalent conditions for hospitalization would seem to warrant serious consideration.

The case in support of technology

Some of the averted costs of technological change are reflected in an analysis of hospitalized illnesses. However, the savings are not perceived for those technologies that eliminate the need for hospitalization, or the illness itself. Therefore, the level of analysis most likely to depict technology in a favorable light is that which is based on total health expenditures. To date, only two studies have assessed the impact of technology on total health care expenditures. Both Victor Fuchs and Selma Mushkin et al. used a residual approach in estimating the impact of technology, with seemingly contradictory results. Fuchs estimated that technology accounted for 0.6 pecentage points of the 8.0 percent annual rate of increase in total health care spending between 1947 and 1967.[17] Mushkin et al., on the other hand, estimated that it *reduced* the annual rate of spending between 1930 and 1975 by 0.4 percentage points.[2]

Both studies estimated the additional impact of technology on health care spending after accounting for increased insurance coverage, higher per capita income, and the greater availability of physician and hospital services. The excess inflation or illness studies did not attempt to isolate the various causes of increased hospital costs. In these studies, changes in the entire end product—expenditures for hospital care—were measured and analyzed. Feldstein and Taylor would agree, however, that much of the availability of "sophisticated" and costly medical care is directly attributable to the pervasive existence of private and public insurance coverage.[10]

There is little argument but that higher family incomes and the growth of third-party coverage have enabled the health industry to purchase more equipment, personnel, and other resources for the provision of health services. Would such expenditures have occurred without the increased availability of high-technology procedures? Such a question cannot be answered using either the excess inflation or the illness approach, but instead must rely on more complicated multivariate models of the nation's health system.

While the residual approach has been used extensively by economists to explain the "extra" impact of technology, it is a methodology with significant limitations. Foremost among them is a difficulty of crucial importance, that of properly specifying the model. Any mistake in specification will affect the residual estimate. Since much of the variation is around a zero residual (a neutral estimate of the impact of technology), even relatively small errors in specification or in the statistics used to estimate the model can lead to the conclusion that technology has had a positive impact on rising health care cost when the true result is negative, or vice versa. This difficulty with specification is aggravated by the problem that new technologies have been widespread as a result of increased demand for and improved financing of health care. Therefore, variables that capture the impact of increased demand of health care will also pick up the effects of technology. For example, increased spending for patients with end-stage renal failure could be attributed to increased financing from Medicare, yet this increased financing resulted primarily from the introduction of a new type of medical technology, renal dialysis. Therefore, while a multivariate model is desirable for isolating the separate effect of technology, measuring it through a residual technique is quite troublesome both statistically and conceptually.

As mentioned previously, the most comprehensive analysis conducted thus far for the impact of technology on total health expenditures has been done by Selma Mushkin and her colleagues at Georgetown University's

Public Services Laboratory. As shown in Table 4, Mushkin disaggregated the factors contributing to the increase in total health expenditures from 1930 to 1975.[2] Of the 3150 percent growth in total health care spending in that period, population and its changing age composition accounted for 19 percent and price changes or inflation contributed another 42 percent, leaving 39 percent to be explained by other factors. The Mushkin et al. residual approach went further and attempted to explain the marginal impact of technology on health spending after accounting for the influence of two "sources of funds" variables, changes in per capita real disposable income, and the growth in third-party payments. Because of the high autocorrelation between the two variables, an assumed income elasticity of 1.0 was used (i.e., a direct proportional relationship between increases in health spending and per capital real disposable income).* This resulted in a derived third-party elasticity of .54; for example, a 10 percent increase in third-party payments leads to a 5.4 percent increase in total health expenditures. When combined, the two sources of funds variables explain 44 percent of the change in spending, leaving a *negative* residue of 5 percent (39 percent from 44 percent), which was attributed to technology.

Mushkin et al. acknowledged the sensitivity of their residual estimate and the fact that the earlier Fuchs study using a similar methodology found the unexplained residual to be positive (Table 5). Mushkin suggests that the differences in results might be explained by the different time periods of the two studies and the use of a different third-party payment variable.

Given the questionable reliability of the residual approach, and the fact that two of the three studies using it arrived at positive estimates, while

* For a more thorough discussion of the effect of changes in family income on health expenditures see John R. Virts, "U.S. Health Care Spending: An Alternative Analysis of Increases," paper presented to the American Enterprise Meeting on Health Costs, Washington, D.C., July 22, 1976.

Table 4[2,18,19]

Factors contributing to the increase in health expenditures, fiscal years 1930-75[a]

Factors	*Total percent change in each of the factors*	*Percent of total rise attributed to each factor*
Total	+3150%	100.0%
Population	+75	16.0%
Price	+328%	42.0%
Income	+121%	23.0%
Aging	+13%	3.0%
Third-party	+200%	21.0%
Residual	-17%	-5.0%

[a] In computing these percentage increases, Social Security estimates for calendar 1929 are used to represent fiscal year 1930. This use of the estimates is made possible because the basic data used in compiling the Social Security estimates for calendar 1929 are from the Committee on Costs of Medical Care study which relates to a 12-month period during 1928-31.

Source of the Data: Marjorie Smith Mueller and Robert M. Gibson, "National Health Expenditures, Fiscal Year 1975," *Social Security Bulletin*, February 1976, pp. 3-20; Barbara Cooper, Nancy Worthington and Mary McGee, *Compendium of National Health Expenditures*, U.S. DHEW, Washington, D.C.: Government Printing Office, January 1976.

Source: Selma J. Mushkin, Lynn C. Paringer, and Milton M. Chen, "Returns to Biomedical Research 1900-1975. An Initial Assessment of Impact on Health Expenditures," Georgetown University, 20 October 1976, p. 6, Table 1.

Table 5
Factors contributing to growth of total health expenditures

	1930–75 annual rate of change	Fuchs study 1947–67 annual rate of change
Total health expenditures	7.70%	8.0%
Accounted for by		
Growth of population	1.2	1.6
Aging of population	.2	—
Rise in price	3.2	3.7
Growth of real income	1.8	2.3
Growth in third-party payments	1.6	—
Decline in quantity demanded due to relative price change	—	−0.2
Unexplained residual	−.5	0.6

Source: Selma Mushkin, Lynn C. Paringer, and Milton M. Chen, "Returns to Biomedical Research 1900–1975: An Initial Assessment of Impacts on Health Expenditures." Georgetown University, 20 October 1976, p. 11, Table 3.

Mushkin et al., using the same model to estimate the marginal impact of technology in the period 1900–1930, achieved results that were inconclusive,[2] it is hard to accept the Mushkin et al. conclusion that technology reduces health outlays. Nevertheless, their study does raise doubts about an uncritical acceptance of the "technology is the culprit behind rising health care costs" position.

Summary and conclusions

The results obtained thus far as to the impact of technology on health care spending would suggest caution in accepting either the Gaus or the Mushkin position uncritically. Statistical problems have prevented very refined measurement techniques from being used to evaluate the impact of technology. The two prime techniques—the excess-inflation approach and the time series multivariate analysis technique—both use the residual method of estimation. That is, whatever cannot be explained with other relevant variables—general inflation, larger than average medical wage increases, changes in the age and sex composition of the United States population, and increased demand for medical services—must at least in part be technologically induced. But the residual approach is really a very crude proxy measure for technology and at best should be used only to establish general direction.

While it is generally agreed that were it not for the pervasiveness of third-party coverage, much high-cost technology would have "sat on the shelf," the reverse is not so obvious; that is, given the extent of third-party coverage, the same amount of money would have been spent for health care without the existence of these new technologies. It is on this point that the excess inflation approach and the multivariate residual approach part company.

Implicit in the Gaus statement is that if the induction of new technologies and the diffusion of existing technologies had not taken place at the rate they did, *less* money would have been spent for hospital care (and perhaps all health care). The Mushkin et al. study suggests that most of the actual spending, if not more, would have taken place without this technology; it just would have gone for other services.

In comparing the indictment against technology derived by Gaus and Social Security against the positive findings of Mushkin et al., two basic differences in study design must be remembered. The Gaus study concentrates on explaining increases in hospital costs only, and for the period beginning in 1965. On the other hand, Mushkin et al. use total health expenditures as a base and derive their estimates over a 40-year time range beginning in 1930. But the hospital is the area where most costly technologies are employed, and the segment of the industry which has witnessed the greatest cost increases in the last decade. It is hard to believe that the "possible" savings due to averted hospitalization could have made up for the large increases in spending. These resource-intensive innovations appear both to have raised the per unit costs of treatment and to have led to the use of more of the most expensive types of treatment. Lewis Thomas has coined the expression "half-way technologies" for therapeutic treatments such as hemodialysis which treat but do not prevent or cure illness.[20] Since the financing system is willing to foot the bill for such treatment modalities, it is no wonder that they have been so extensively used. Furthermore, the utilization of such procedures and the purchase of expensive equipment have too often occurred without serious consideration of their cost effectiveness.

What of the future? The key to understanding whether technology has been and will continue to be "the culprit behind rising health care costs," and, if so, what to do about it is to find the answers to three critical questions:

1. Has the existence of technological innovations in the health field in recent years led to more or less spending for health services, given the greater capacity of patients to afford more costly services because of the growth in per capita income and the increasing availability of third-party health coverage? More importantly, what do such past trends portend for the future?

2. Is the spending of resources for technology and related activities yielding marginal benefits commensurate with the value that these resources could generate if they were rechanneled to other forms of health care, for example, more preventive or home health services?

3. Should the government consider adopting tighter controls on the development and diffusion of technological innovations in the health system, including a reduced rate of growth in the financing of high technology health services?

Question 3 is a legitimate issue to discuss even if it is determined that the net impact of increased spending for technology has been to reduce total expenditures for health services, that is, provided one believes that government can be effective in limiting such spending and in rechanneling such funds into higher pay-off areas.

We would hope that these questions would form the basis of much of the discussion for the remainder of this conference.

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Changes in the use of ancillary services for "common" illness

Anne A. Scitovsky

Introduction

Most of the discussions of the effects of technological change on the costs of medical care, and of ways of controlling costs, have centered on high-cost innovations such as organ transplants, open-heart surgery, renal dialysis, and brain and body scanners. The less dramatic changes that have occurred in the treatment of the common, everyday illnesses that make up the bulk of medical care have received relatively little attention. Yet, taken together, these changes may well have had as important an effect, if not a greater one, on medical care costs than the more spectacular innovations.

The cost-of-illness studies that have been conducted at the Palo Alto Medical Research Foundation (PAMRF), based on data of patients treated at the Palo Alto Medical Clinic (PAMC), shed some light on how changes in the treatment of a number of common conditions have affected average costs per episode of illness.[1 2] We found that, with minor exceptions, cost-raising changes in treatment outweighed cost-saving changes in both periods covered by the studies—1951 to 1964 and 1964 to 1971—so that the net effects of changes in treatment were generally cost-raising. Furthermore, we found that the main cost-raising factor in both periods was the steady increase in the use of ancillary services such as laboratory tests and X-rays, both in and out of the hospital. Tables 1 and 2 summarize some of the findings from our studies. Table 1 shows that, in most instances, the number of ancillary services per episode of illness rose steadily over the entire 20-year period 1951 to 1971. For example, the number of laboratory tests per case of uncomplicated appendicitis rose from 4.7 tests per case in 1951 to 7.3 tests in 1964 to 9.3 tests in 1971. Tests per case of perforated appendicitis increased from 5.3 tests in 1951 to 14.5 in 1964 to 31.0 in 1971, and tests per maternity case rose from 4.8 in 1951 to 11.5 in 1964 to 13.5 in 1971. Although the rise in X-rays per case was less spectacular, in most instances increases were found. The same was true for other ancillary services such as electrocardiograms.

Table 2 indicates what this meant in terms of costs. It shows the increased costs of ancillary services from 1951 to 1964, and from 1964 to 1971 (inpatient and outpatient) per episode of illness, as a percentage of the earlier year's use of such services in the later year's prices. Thus we see that in 1964 ancillary services used in the treatment of the various conditions cost anywhere from 26 percent (simple appendicitis) to 147 percent (maternity care) more than they would have cost if the 1951 pattern of services had

Table 1[1]

PAMRF cost-of-illness studies: Number of ancillary services per case, by type of service, selected illnesses, 1951, 1964, and 1971

Type of service and illness	*1951*	*1964*	*1971*
LABORATORY TESTS			
Appendicitis, simple	4.7	7.3	9.3
Outpatient	1.4	1.9	2.3
Hospital	3.3	5.4	7.0
Appendicitis, perforated	5.3	14.5	31.0
Outpatient	2.8	2.7	6.8
Hospital	2.5	11.8	24.2
Maternity care	4.8	11.5	13.5
Outpatient	4.4	9.5	11.9
Hospital	.4	2.0	1.6
Cancer of the breast	5.9	14.8	27.4
Outpatient	1.3	4.3	16.9
Hospital	4.6	10.5	10.5
Myocardial infarction	—	37.9	48.5
Outpatient	NA	5.5	3.3
Hospital	NA	32.4	45.2
Pneumonia, not hospitalized	NA	3.0	2.3
Pneumonia, hospitalized	—	6.7	18.6
Outpatient	NA	1.7	5.8
Hospital	NA	5.0	12.8
Duodenal ulcer, not hospitalized	NA	5.4	5.4
Duodenal ulcer, hospitalized	—	22.7	27.3
Outpatient	NA	6.0	6.2
Hospital	NA	16.7	21.1
X-RAYS			
Cancer of the breast[a]	2.4	13.0	12.9
Diagnostic	.7	2.0	2.3
Radiotherapy	1.7	11.0	10.6
Forearm fracture, cast only	2.3	2.3	2.2
Forearm fracture, closed reduction, no general anesthetic	3.7	2.7	3.9
Forearm fracture, closed reduction, general anesthetic	2.0	5.4	6.4
Outpatient	1.6	2.7	4.1
Hospital	.4	2.7	2.3
Myocardial infarction	—	1.3	6.3
Outpatient	NA	.1	.4
Hospital	NA	1.2	5.9
Pneumonia, not hospitalized	NA	2.0	1.8
Pneumonia, hospitalized	—	2.5	3.6
Outpatient	NA	1.3	1.6
Hospital	NA	1.2	2.0
Duodenal ulcer, not hospitalized	NA	2.4	2.2
Duodenal ulcer, hospitalized	—	2.7	3.1
Outpatient	NA	1.7	.9
Hospital	NA	1.0	2.2
ELECTROCARDIOGRAMS			
Myocardial infarction	—	5.4	9.0
Outpatient	NA	1.4	1.7
Hospital	NA	4.0	7.3
INHALATION THERAPY			
Myocardial infarction	NA	12.8	37.5
Pneumonia, hospitalized	NA	3.8	2.6

[a]*All are outpatient services.*

Table 2[1]

PAMRF cost-of-illness studies: 1964 actual average costs of ancillary services as percentage of estimated 1964 costs with 1951 pattern of ancillary services, and 1971 actual average costs as percentage of estimated 1971 costs with 1964 pattern of ancillary services, selected illnesses

1964 actual costs as percentage of 1964 estimated costs, 1951 usage pattern	
Appendicitis, simple	126.2%
Appendicitis, perforated	144.4
Maternity care	246.6
Cancer of the breast	150.9 (excluding radiotherapy)
	258.8 (including radiotherapy)
Forearm fractures, general anesthetic	174.8
1971 actual costs as percentage of 1971 estimated costs, 1964 usage pattern	
Appendicitis, simple	140.7%
Appendicitis, perforated	175.5
Maternity care	104.1
Cancer of the breast, including radiotherapy	104.9
Forearm fractures, general anesthetic	114.1
Forearm fractures, no general anesthetic	148.3
Myocardial infarction	186.3
Pneumonia (not hospitalized)	96.6
Duodenal ulcer (not hospitalized)	94.8

prevailed. Similarly, in 1971 (except for pneumonia and duodenal ulcer, where they cost slightly less), they cost 4 percent (maternity care) to 86 percent (myocardial infarction) more than they would have cost if the 1964 pattern of use had prevailed.

These findings strongly suggested the need for further exploration of the impact on costs of the use of ancillary services in the treatment of common illnesses. Because of lack of other data on costs per episode of illness, this paper concentrates on ancillary services in ambulatory care, since such care can be assumed to be largely for common conditions. The question this paper addresses is: How much of our medical care dollar are we currently spending for ancillary services in ambulatory care, and how does this compare with what we might be spending if the use of outpatient ancillary services had remained at the mid-1960s level? Concentration on the ambulatory care sector does not mean, however, that the change in the hospital sector can be neglected. If anything, judging by the PAMC cost-of-illness data, the increase in the use of ancillary services has been even greater in the inpatient care of common conditions. Though that area is beyond the scope of this paper, it deserves further study.

Estimates of expenditures for ancillary services in ambulatory care

Before discussion, a few comments about my estimates are in order. These estimates are for outpatient laboratory tests and X-rays only. They are based on utilization and charge data from a number of providers, some of them prepaid health plans, others fee-for-service providers. Utilization data from health plans can be expressed either in terms of number of tests or procedures per enrollee per year, or in terms of number of tests or procedures per physician office visit or DOV (doctor office visit, the term generally used). The former is obviously preferable as a basis for national estimates, although even this measure does not provide strictly comparable data because of differences in the patient and physician populations between different plans. However, this measure is not available in fee-for-service settings where there is no population base to which to relate the volume of services. Since there were more data available on the number of laboratory tests and X-rays per DOV than per enrollee, the per DOV measure has been used.

It must be borne in mind, however, that this measure has some shortcomings. It does not take account of differences between providers in the composition of their physician populations by field of specialty, nor of changes over time in the composition by field of specialty for a single provider. For example, if different providers have different proportions of physicians in fields of specialty that generate few if any ancillary services (i.e., ophthalmologists, psychiatrists), the data are not strictly comparable. Furthermore, if there is a change over time in the number of physician office visits per episode of illness, estimates using this measure will be biased. For example, if the number of physician office visits per episode of illness declines over time, the measure results in an overestimate of the increase in the total number of tests performed. While it is possible to correct for some of these shortcomings, given sufficient time and additional data, no attempt to do so has been made in this paper.

Using data on the number of tests per DOV required an estimate of the total number of physician office visit in the United States. The National Center for Health Statistics (NCHS) figures for visits in physicians' offices, hospital outpatient clinics, and emergency rooms have been used.[3] In 1975, there were 854.3 million such visits, or 4.1 visits per person. Excluded from this figure are physician visits in company and industrial health centers, visits in miscellaneous other locations, home visits, and telephone consultations, which in 1975 together totalled slightly over 200 million. Since these visits and consultations probably generate at least some ancillary services, the estimates presented here tend to understate the actual volume of and expenditures for outpatient laboratory tests and X-rays, although lack of data makes it impossible to say by how much.

Furthermore, because the estimates are limited to outpatient laboratory tests and X-rays, they do not represent total expenditures for all outpatient and ancillary services. On the basis of data from the PAMC, it seems reasonable to estimate that expenditures for laboratory tests and X-rays must be increased by at least 25 percent to yield estimates of total expenditures for all outpatient ancillary services. The PAMC data show that for the past ten years gross revenue from laboratory tests and X-rays has accounted for about 70 percent of total gross revenue from all ancillary services. However, the PAMC probably provides a higher proportion of miscellaneous other ancillary services (such as radiation therapy, diet service, pulmonary function test and screening, physical therapy) than is available in the ambulatory care sector as a whole. Therefore, it seems reasonable to assume that national expenditures for outpatient laboratory tests and X-rays account for about 80 percent of total national expenditures for outpatient ancillary services.

Finally, these estimates must be regarded as tentative. They are based on data from a few providers whose patient and physician populations differ in many respects. Despite these limitations, however, it seems highly likely that actual expenditures for outpatient laboratory tests and X-rays lie somewhere between the low and high estimates arrived at in this study. The medium estimate probably comes closest to actual expenditures.

Laboratory tests

The only national data currently available on the volume of outpatient laboratory tests come from the National Ambulatory Medical Care Survey of 1973 and show that in 19.6 percent of physician office visits a laboratory procedure was ordered or provided.[4] The Survey covered only patient encounters in the offices of physicians classified by the American Medical Association or the American Osteopathic Association as "office based, patient care." Although NCHS, which conducted the survey, estimates that this included about 70 percent of all ambulatory encounters, important segments of ambulatory care, especially care rendered in hospital outpatient clinics and emergency rooms, were omitted. In addition, the figure does not tell us how many tests were performed. National data on the costs of or charges for outpatient laboratory tests are nonexistent.

Tables 4 and 5 show data on outpatient laboratory tests obtained from various providers of medical care services. Table 4 shows the number of laboratory procedures, and Table 5, the number of laboratory tests per DOV and, where applicable, per enrollee per year. A procedure is defined as a laboratory service for which there is usually a single charge in care settings where services are billed for, but which may consist either of a single test (i.e., a white blood count) or a panel of tests (i.e., a complete blood count, or CBC, and the automated survey panels, or SPs). Ten or 15 years ago this distinction was not very important, because the only frequently performed laboratory procedure consisting of multiple tests was a CBC. In recent years, however, with the introduction of automated laboratory equipment, it has assumed major importance. Some of the data sources count the number of laboratory procedures, others the number of laboratory tests.* The number of actual laboratory tests is clearly the better measure. Accordingly, wherever possible, the actual number of laboratory tests for 1975 has been obtained from those sources that count the number of laboratory procedures. Table 3, for 1975, illustrates the great differences that exist between different providers in the ratio of tests to procedure. The differences reflect partly the degree of automation of their laboratories, and partly their practice and billing

* The PAMC is the only one of the sources used here that routinely collects data on the number of laboratory visits (patients), the number of laboratory procedures and the number of laboratory tests.

Table 3
Laboratory tests and procedures, 1975

	Number of laboratory tests per laboratory procedure	Laboratory procedures consisting of multiple tests as a percentage of all laboratory procedures		
		Total	CBC	SP
Palo Alto Medical Clinic, 1975	3.4	22.7%	20.1%	2.6%
Columbia (Md.) Medical Plan, 1975	1.5	9.9%	8.2%	1.7%
University of California, San Francisco Outpatient Clinics, 1975	2.6	15.1%	1.5%	13.6%
University of California, San Francisco Outpatient Clinics, 1976	4.9	59.0%	15.8%	43.2%

systems. Data from 1976 for the University of California, San Francisco outpatient clinics have been included because they illustrate how rapidly changes in automation can affect the number of tests per laboratory procedure.**

The first column of Table 4 shows the number of laboratory procedures per DOV for a number of providers and/or health plans for selected years in the period 1964 to 1975. The only provider for which data are available for the entire period is the PAMC. There appears to have been little change in the number of procedures per DOV at the PAMC during this period, the figures fluctuating between a low of .55 and a high of .72. By contrast, the data for the other providers show a steady upward trend. The Kaiser-Oregon data show an increase from .76 laboratory procedures per DOV in 1968 to .91 in 1971. Similarly, the data for both the University of California, San Francisco outpatient clinics and the Columbia (Maryland) Medical Plan show a steady increase in the period 1971 to 1975, from .47 laboratory procedures per DOV to .84 for the former, and from .48 to .73 for the latter. Including the data for the Group Health Cooperative of Puget Sound (Seattle Prepaid Health Care [Model City] Project) and for the King County Medical/Blue Cross Plan of Washington and Alaska for the years 1971 through 1974, the average number of laboratory procedures per DOV ranged between .63 and .85 in 1974/1975.

Table 5 shows the data on actual laboratory tests for selected years during the same period. As in Table 4, the first column of the table presents the data in terms of number per DOV; the second in terms of number per enrollee per year. For the three providers concerning whom data are available for at least some of the years 1964 to 1975, the figures for tests per DOV show a steady substantial increase over the span. Data for the PAMC (all patients) show that the number of laboratory tests per DOV rose from .88 in 1964 to 1.61 in 1970 to 2.11 in 1975. Similarly, data for the PAMC-Stanford University

** According to sources at the University of California, San Francisco, the increase in the number of CBCs reflects a change in billing procedures. Until 1976, in most instances, each of the tests included in a CBC was billed separately; as of 1976, a single charge for the CBC has been made.

Table 4[a]

Number of outpatient laboratory procedures per physician office visit and per enrollee per year, selected providers and plans, 1964–1975

Provider and/or plan, and year	Number of outpatient laboratory procedures: Per doctor's office visit (DOV)	Per enrollee
Palo Alto Medical Clinic[a]		
1964	.70	NA
1966	.57	NA
1970	.63	NA
1971	.69	NA
1972	.55	NA
1973	.58	NA
1974	.72	NA
1975	.62	NA
Kaiser-Oregon Region		
1968[b]	.76	2.51
1970[b]	.89	3.01
1971[c]	.91	3.12
University of California, San Francisco outpatient clinics[d]		
1971	.47	NA
1972	.56	NA
1975	.84	NA
Columbia (Md.) Medical Plan		
1971	.48	2.49
1972	.59	3.05
1973	.72	3.68
1974	.78	3.75
1975	.73	3.72
Group Health Cooperative of Puget Sound—Model City Project[e]		
1971–74 (average)	.85	3.82
King County Medical/Blue Cross Plan of Washington and Alaska—Model City Project[e]		
1971–74 (average)	.63	2.87

[a]Data refer to all patients.

[b]*Source:* Freeborn, DK, et. al.[8]

[c]*Source:* Some information Descriptive of a Successfully Operating HMO.[9]

[d]Data refer to fiscal years.

[e]Data are from a study of the Seattle Prepaid Health care Project under the direction of Dr. William C. Richardson. They refer solely to the Project's experience with Group Health Cooperative of Puget Sound and King County Medical/Blue Cross plan of Washington and Alaska

prepaid plan show an increase from .79 in 1966 to 2.33 in 1972 to 2.82 in 1974. Data for a fourth provider, Health Insurance Plan of Greater New York (HIP), for the years 1964 to 1970 only, show a rise from .88 tests per DOV in 1964 to 1.21 in 1970.

It is of interest to note that despite the diversity of the providers and of their patient populations, the figures of tests per DOV in 1974/1975 are strikingly similar. Four of the six providers for whom we have data show about 2.0 laboratory tests per DOV. The exception on the low side, with

Table 5[19]

Number of outpatient laboratory tests per doctor's office visit and per enrollee per year, selected providers and plans, 1964-1976

Provider and/or plan, and year	*Number of outpatient laboratory tests* — *Per doctor's office visit (DOV)*	*Per enrollee*
Palo Alto Medical Clinic[a]		
1964	.88	NA
1966	.77	NA
1968	1.07	NA
1970	1.61	NA
1971	1.64	NA
1972	1.70	NA
1973	1.71	NA
1974	2.10	NA
1975	2.11	NA
1976	2.12	NA
Palo Alto Medical Clinic-Stanford University prepaid plan		
1966	.79	3.79
1968	.86	3.09
1972	2.33	7.90
1974	2.82	9.67
Kaiser-Northern California-Stanford University prepaid plan		
1974	1.98	5.96
Health Insurance Plan of Greater New York[b]		
1964	.88	3.48
1966	.94	3.66
1968	1.01	3.70
1970	1.21	4.01
Medical Care Group of Washington University, St. Louis		
1974	2.04	10.24
Columbia (Md.) Medical Plan		
1975	1.07	5.42
University of California, San Francisco outpatient clinics[c]		
1975	2.14	NA
1976	4.12	NA

[a]Data refer to all patients.

[b]*Source:* HIP Statistical Reports[18] No reports have been published since 1970.

[c]Data refer to fiscal years.

1.07 tests per DOV, is a relatively new plan, the Columbia (Maryland) Medical Plan; the exception on the high side, with 2.82 tests per DOV, is the PAMC-Stanford University plan. Accordingly, 2.0 tests per DOV have been chosen as the basis for an estimate of the volume of tests. To be on the conservative side, however, an estimate has also been made assuming 1.5 laboratory tests per DOV, although both the data on tests per DOV and data from our various cost-of-illness, coinsurance and medical care utilization studies make it appear doubtful that the actual rate in 1975 was that low.

An estimte of 2.0 laboratory tests per DOV in 1975 may appear too high in view of the finding of the 1973 National Ambulatory Medical Care Survey cited earlier that only 19.6 percent of physician office visits led to a laboratory procedure. There are two reasons why I do not think this figure excessive. First, PAMC data show that in the period 1970 to 1976 the percentage of office visits leading to a laboratory procedure was almost identical to that shown by the National Ambulatory Medical Care Survey of 1973, fluctuating between a low of 19.0 percent (in 1971) and a high of 20.4 percent (in 1972). Secondly, the National Ambulatory Medical Care Survey, as mentioned earlier, omits an important segment of physician outpatient visits, for example, visits in hospital clinics and emergency rooms. In 1975, these visits amounted to 13.9 percent of all physician outpatient visits and 16.0 percent of the combined total of physician office visits and visits in hospital outpatient clinics and emergency rooms, the figure being used in these estimates. While there are no readily available data to substantiate the hypothesis, it seems likely that these visits generate more tests per visit than do visits in physicians' offices. Access to ancillary services is easier in a hospital setting than in a physician's office, the staff is probably more test-oriented than are physicians in nonhospital-based settings, and the patient population may be sicker, especially patients using an emergency room. Thus an estimate of 2.0 tests per DOV which includes visits in hospital clinics and emergency rooms seems reasonable.

To translate the estimated volume of tests into an estimate of total 1975 expenditures for outpatient laboratory tests required an estimate of the average charge per test. This proved problematical, not only because of very limited data, but because the charge per test depends largely on the extent to which a given provider performs multiple-test procedures, especially the automated survey panels (Serial Multiple Analysis (SMA) 6s and 12s). For example, at the PAMC the charge for a 12-test survey panel in 1975 was $18.50, or about $1.50 per test. If these 12 tests had been done separately on different days, the charge would have been $88.50, or about $7.40 per test; if done separately on the same patient on the same day, $71.00, or about $6.00 per test. Obviously the greater the use of automated procedures, the lower the average charge per test.

The only data on average charges or costs of laboratory tests which were possible to obtain were:

- $2.50 PAMC, 1975 (average charge)
- $2.53 Medical Care Group of Washington University, St. Louis, 1974 (average charge)
- $2.01 Group Health Cooperative of Puget Sound—Model City Project, 1974 (average cost for the entire Cooperative)
- $3.62 King County Medical Blue Cross of Washington and Alaska—Model City Project, 1974 (average charge paid by the Project)

Data on the use of multiple-test procedures, especially automated survey panels, by these groups are too fragmentary to help much in the selection of an appropriate figure. I have therefore again made two estimates, one of $2.00 per test, the other of $2.50 per test.

To arrive at estimates of total national expenditures for outpatient laboratory tests in 1975, my estimates of the number of tests per DOV and the average charge per test were combined in three ways so as to arrive at a low, a medium, and a high estimate:

- Low .... 1.5 laboratory tests per DOV, $2.50 average charge
- Medium .... 2.0 laboratory tests per DOV, $2.00 average charge
- High .... 2.0 laboratory tests per DOV, $2.50 average charge

The higher average charge estimate of $2.50 per test was combined with the lower estimate of number of tests per DOV on the assumption that the lower volume of tests reflects a slightly lower use of automated laboratory procedures and hence a somewhat higher charge per test. Multiplying these estimates by the NCHS 1975 figure of 854.3 million physician office visits[3] gives the following estimates of total national expenditures for outpatient laboratory tests in 1975:

- Low estimate .... $3,204 million
- Medium estimate .... $3,417 million
- High estimate .... $4,272 million

These are not trifling amounts, and I shall comment on them further below.

How much more are we spending for outpatient laboratory tests than we would be spending if the mid-1960s rate of laboratory tests per DOV had prevailed in 1975? To be conservative in the sense of not overestimating the increase in expenditures, I am assuming a rate of one test per DOV, a figure which seems reasonable on the basis of the data we have for the mid-1960s. Since this rate implies a low use of automated procedures, the average charge per test would probably be at least $2.50 and possibly $3.00, if not slightly more. With an estimated 854.3 physician office visits a year, this would mean current expenditures of $2,136 million (at $2.50 per test) to $2,563 million (at $3.00 per test). In other words, even the low 1975 estimate of national expenditures for outpatient laboratory tests is between $640 million and $1 billion higher, and the high one between $1.7 billion and $2.1 billion higher, than estimated expenditures in 1975 would have been if mid-1960s patterns of use of outpatient laboratory tests had then prevailed.

X-rays

There have been three nationwide surveys of the volume of X-ray visits in the United States: for July 1960–June 1961, April–June 1964, and April–September 1970. They show a steady increase in the volume of X-ray visits from 47.0 visits per 100 persons in 1960–61, to 49.8 visits in 1964, to 55.9 visits in 1970.[11] The data for 1970 also show that on the average an X-ray visit involved 1.3 X-ray examinations,[11] which translates into 72.7 X-ray examinations per 100 persons.

Unfortunately, while these surveys distinguish between X-ray visits and examinations in hospitals, physicians' offices, mobile units, and other settings (schools, health departments, industrial clinics), they do not distinguish between hospital inpatient and hospital outpatient X-ray visits. However, on the basis of data from the American Hospital Association,* it is possible to estimate the percentage of hospital X-ray examinations in 1970 which were outpatient X-rays. These data show that in 1971 (the earliest year for which data are available), 40.2 percent of hospital X-ray examinations were outpatient examinations. Applying this figure to the national hospital X-ray data for 1970 gave figures of 17.6 hospital outpatient X-ray examinations per 100 persons, and a total of 48.7 outpatient X-ray examinations per 100 persons including X-ray examinations in physicians' offices and other locations. This is equivalent to 13.3 X-ray examinations per 100 DOV's in 1970.

As in the case of outpatient laboratory tests, the only national data on outpatient X-rays alone come from the National Ambulatory Medical Care Survey of 1973. They show that in 7.1 percent of physician office visits, an X-ray procedure was ordered or provided.[4] Even if we assume the 1970 national ratio of 1.3 X-ray examinations per X-ray visit, this comes to only 9.2 X-ray examinations per 100 DOV's, a figure which is low compared to the number of X-ray procedures per 100 DOV's estimated on the basis of the national data for 1970. Again, one possible explanation is that the 1973 survey probably resulted in an underestimate of the volume of outpatient ancillary services because it did not include visits in hospital outpatient clinics and emergency rooms, where the ratio of tests per visit is probably higher than in physicians' offices.

The National Ambulatory Medical Care Survey figure is also low compared to the rates for a number of providers shown in Table 6. The 1974-1975 rates for four of the seven providers for whom I was able to obtain data ranged from 13.5 to 16.9 X-ray examinations per 100 DOVs, with a fifth provider reporting a very much higher rate of 24.8 X-rays per 100 DOVs for 1971. Only two providers reported lower figures (8.5 and 10.2 X-ray visits per 100 DOVs) which are close to the National Ambulatory Medical Care Survey figure.

For an estimate of national expenditures for outpatient X-ray examinations, the figure from the National Ambulatory Medical Care Survey would would appear to be the figure to use because it is derived from a nationwide survey. However, both the estimated rate of X-rays based on the 1970 national survey, and the rates of the providers strongly suggest that the national rate was higher than that shown by the Survey. It is true that all the data shown in Table 6, with the exception of those for the PAMC, are from prepaid health plans. It can be argued that their members probably use more services than the population at large, although even this is not

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*I wish to thank Mr. William Michela for this information. The American Hospital Association data show that outpatient X-ray examinations constituted between 37.9 percent and 43.2 percent of all hospital X-ray examinations, depending on the size of the hospital. I have used the figure for hospitals with 100 to 199 beds.

Table 6
Number of outpatient X-ray procedures per 100 physician office visits and per 100 enrollees per year, selected providers and plans, 1964–1975

Provider and/or plan, and year	Number of outpatient X-ray procedures: Per 100 doctor's office visits (DOV)	Per 100 enrollees
Palo Alto Medical Clinic[a]		
1964	11.8	NA
1966	12.4	NA
1968	12.2	NA
1970	14.6	NA
1971	14.9	NA
1972	16.5	NA
1975	16.6	NA
Palo Alto Medical Clinic-Stanford University prepaid plan		
1966	13.1	63.3
1968	14.0	50.4
1972	15.9	54.0
1974	16.9	59.3
Kaiser-Northern California-Stanford University prepaid plan		
1974	15.0	44.8
Kaiser-Oregon Region[b]		
1971	24.8	85.1
Group Health Cooperative of Puget Sound-Model City Project[c]		
1971–1974 (average)	8.5	36.0
King County Medical/Blue Cross of Washington and Alaska—Model City Project		
1971–1974 (average)	13.5	60.0
Columbia (Md.) Medical Plan[d]		
1971	6.7	35.1
1972	7.8	40.1
1973	8.0	40.9
1974	8.4	40.4
1975	10.2	51.6
1976	10.8	57.8

[a]Data refer to all patients.

[b]Source: Some Information Descriptive of a Successfully Operating HMO.[9]

[c]Data are from a study of the Seattle Prepaid Health Care Project under the direction of Dr. William C. Richardson. They refer solely to the Project's experience with Group Health Cooperative of Puget Sound and King County Medical/Blue Cross of Washington and Alaska.

[d]The figures for 1972 through 1974 are very tentative.

quite certain, considering the extent of present-day health insurance coverage. But even if health plan members were heavier users of X-ray services, this possible upward bias may be offset, at least in part, by the fact that none of the plans had members aged 65 years or older. According to the data from the National Ambulatory Medical Care Survey, persons aged 65 and over have a considerably higher use of outpatient X-ray services than younger persons: 8.0 percent of their physician visits led to an X-ray visit, compared to 6.9 percent of the visits of those under 65 years.[4] Therefore, I have chosen a rate of 12 X-ray examinations for 100 DOVs as a conservative estimate and a rate of 14 X-ray examinations as a somewhat higher estimate. The lower rate is equal to 49.0 X-ray examinations per 100 persons in 1975,* the higher to 57.2 X-ray examinations.

The data on average costs of charges per X-ray examination that I was able to obtain are shown below:

- $28 PMC, 1975 (average charge)
- $16 Group Health Cooperative of Puget Sound—Model City Project, 1974 (average cost for the entire Cooperative)
- $20 King County Medical/Blue Cross of Washington and Alaska—Model City Project, 1974 (average charge paid by the Project)

The PAMC Figure may be higher than the figures for the other two providers because the PAMC probably performs a smaller percentage of relatively low-priced X-rays, especially routine chest X-rays. I have therefore based my estimates on the data from the other providers, selecting an average charge of $16 per X-ray as a conservative estimate and of $20 per X-ray as a somewhat higher estimate.

As in the case of laboratory tests, estimates of the volume of X-rays and of average charges per X-ray have been combined in three ways so as to obtain a low, a medium, and a high estimate:

- Low .... 12 X-ray examinations per 100 DOVs, $16 average cost
- Medium .... 12 X-ray examinations per 100 DOVs, $20 average cost
- High .... 14 X-ray examinations per 100 DOVs, $20 average cost

Multiplying these estimates by the total number of physician office visits in 1975 (854.3 million) results in the following estimates of total national expenditures for outpatient X-ray examinations:

- Low estimate .... $1,640 million
- Medium estimate .... $2,050 million
- High estimate .... $2,392 million

Estimating how much more was spent for outpatient X-ray examinations in 1975 than would have been spent if the X-ray utilization rates of the mid-1960s had prevailed is problematical, because only the PAMC time trend data are firm. Sources at the Columbia (Maryland) Medical Plan stated that their data for the early 1970s were not very reliable. The PAMC-Stanford University prepaid plan data are seriously affected by the introduction of a 25 percent coinsurance provision in 1967, applying to all physician

*It will be noted that this is almost identical to the rate estimated for 1970 on the basis of the 1970 national survey of X-ray visits. The reason this rate corresponds to 12.0 X-rays per 100 DOVs in 1975 and to 13.3 in 1970 is the difference in the physician utilization rates between the two years: in 1970 there were 3.7 visits per person in physicians' offices and hospital outpatient clinics and emergency rooms, while in 1975 this figure was 4.1. (Data for 1970 on visits in physicians' offices and hospital clinics and emergency rooms based on personal communication from the National Center for Health Statistics.)

and outpatient ancillary services. This led to a substantial decline in the number of office visits per enrollee and to a somewhat smaller drop in X-ray examinations per enrollee in 1968 (which explains why Table 6 shows a small increase in the number of X-rays per 100 DOVs but a drop in X-rays per 100 enrollees for 1968). Thus we have only the PAMC data for an estimate. These show that the X-ray utilization rate in 1964 was about 30 percent below the 1975 rate. If we assume that this ratio held for the ambulatory care sector as a whole, we spent from $500 million to $700 million more for outpatient X-rays in 1975 than if the 1964 use pattern of outpatient X-ray examinations had prevailed.

Estimated expenditues for outpatient laboratory tests and X-rays as a percentage of selected types of health care expenditures

To give my estimates of expenditures for outpatient laboratory tests and X-rays some perspective, Table 7 shows what they amount to as a percentage of estimated national expenditures for outpatient physician and ancillary services (column 1), national expenditures for physician and outpatient ancillary services excluding hospital outpatient services (column 2), and total national personal health care expenditures (column 3). The figures in

Table 7[12]

Estimated national expenditures for outpatient laboratory tests and outpatient X-rays as a percentage of selected national health care expenditures, 1975

		Estimated expenditures[a] *as a percentage of*		
	Estimated expenditures (millions of $)	*(1) Estimated national expenditures for outpatient physician and ancillary services ($19,083 million)*	*(2)*[b] *Total national expenditures for physician services ($22,925 million)*	*(3)*[b] *Total national personal health care expenditures ($105,745 million)*
Low estimate				
Laboratory tests	3,204	16.8	14.0	3.0
X-rays	1,640	8.6	7.2	1.6
Total	4,844	25.4	21.1	4.6
Medium estimate				
Laboratory tests	3,417	17.9	14.9	3.2
X-rays	2,050	10.7	8.9	1.9
Total	5,467	28.6	23.8	5.2
High estimate				
Laboratory tests	4,272	22.4	18.6	4.0
X-rays	2,392	12.5	10.4	2.3
Total	6,664	34.9	29.1	6.3

[a]Percentage may not add up to totals because of rounding

[b]*Source:* Gibson and Mueller: National health expenditures, fiscal year 1976.[13]

columns 2 and 3 are based on the figures published by the Social Security Administration for fiscal year 1975,[5] while the figures in column 1 are based on an estimate of total expenditures for all outpatient physician and ancillary services. I arrived at this estimate by excluding from the national figure for physician expenditures ($22,925 million) the estimated expenditures for physician inpatient services (42 percent of the total, based on the findings of Ronald Andersen's 1970 survey)[6] and adding to it the estimated expenditures for hospital outpatient services (12 percent of total hospital expenditures, based on the ratio of gross outpatient revenue to total gross revenue of community hospitals in 1975 as estimated by the American Hospital Association).[7]

As the table shows, according to my estimates between $4.8 and $6.7 billion may have been spent for outpatient laboratory tests and X-rays in 1975. This amounts to 25 percent to 35 percent of estimated expenditures for outpatient physician and ancillary services, 21 percent to 29 percent of expenditures for physician and outpatient ancillary services excluding hospital outpatient services, and 5 percent to 6 percent of total personal health care expenditures in 1975. According to the medium estimate, which probably comes closest to the actual figures, expenditures for outpatient laboratory tests and X-rays would be equal o 29 percent of estimated expenditures for outpatient physician and ancillary services, 24 percent of expenditures for physician and outpatient ancillary services excluding hospital outpatient services, and 5 percent of total personal health care expenditures. To make some further comparisons, they correspond to about 70 percent of total 1975 expenditures for dentists' services, over one-half of all expenditures for drugs and prescriptions, and about 60 percent of total nursing home expenditures.[5] These are substantial sums, especially when we remember that expenditures for outpatient laboratory tests and X-rays probably account for only about 80 percent of total expenditures for all outpatient ancillary services. Thus total expenditures for outpatient ancillary services may have ranged from $6.1 billion to $8.3 billion in 1975, or between 6 percent and 8 percent of total personal health care expenditures.

It may be argued that these estimates (quite apart from the question of their accuracy) overstate the costs (and the increase in costs) of ancillary services, since ancillary services may have been substituted for physician services or may have led to a reduction in the average duration of a physician visit. This is a possibility, but to the best of my knowledge, there are no data to support either hypothesis. The cost-of-illness data on average number of physician visits per episode of illness are inconclusive. In the period 1964 to 1971, the average number of physician visits per episode stayed much the same for otitis media, simple appendicitis, maternity care, and the simplest kind of forearm fractures. It rose slightly for perforated appendicitis and the more serious types of forearm fractures, and declined for cancer of the breast, myocardial infarction, duodenal ulcer, and pneumonia.[1] Further study of this problem, as well as of possible changes in the average duration of physician visits (a subject on which we have no data at all), seems indicated.

It is also possible, however, that my estimates understate expenditures for ancillary services. It has been suggested to me that the increased use of laboratory tests is likely to lead to an increase in "false positives," which then necessitate additional physician visits.* It is an interesting suggestion which also deserves further study.

Conclusion

It is hoped that this paper has shown convincingly that when the effect of technological change on medical care costs is examined, it is not enough to look only at the spectacular innovations such as brain scans, renal dialysis, open-heart surgery, and so forth, important as these are. The changes going on in the treatment of common conditions, which require less spectacular medical intervention and which, taken together, probably account for the biggest share of our expenditures for medical care, must be examined far more closely than they have been to date. In particular, the use of ancillary services in the treatment of these conditions needs more attention. First and foremost, additional data are required to fill the enormous data gaps which this paper has shown to exist in the area. Data are needed on the use of ancillary services in different practice settings, by field of specialty of the physician, by type and size of hospital, and by some selected diagnoses.

What is also needed, of course, is an evaluation by the medical profession of the relation between the use of ancillary services and the quality of care. Is more care—more laboratory tests per case, more X-rays, more electrocardiograms—really better care? If cost-benefit analyses of high-cost technological innovations have been scarce, they have been nonexistent in this less dramatic area.

This leads to a final question. If such evaluations should show that there is very little return for all the money spent for additional diagnostic tests and therapeutic procedures, what can be done? As a first step, the relationship between the use of ancillary services and the danger of malpractice suits needs close study. Physicians frequently give a fear of malpractice suits as the reason for ordering tests and procedures which have little justification on purely medical grounds. While this may be a factor, it is unlikely to be the sole or even the main reason for the increased use of ancillary services. Nevertheless, revamping the way in which malpractice complaints are handled might be of some help. A number of suggestions for doing so have been made, such as removing them from the traditional legal system and handling them like Workmen's Compensation claims.

What can be done beyond this is a problem. It may be feasible to control the number of brain scanners or intensive care beds. How to control physicians' use of ancillary services is another matter. It will be interesting to see what happens to the use of ancillary services in hospitals under President Carter's proposed plan to limit the increase in hospital expenditures to 9 percent. When it comes to the ambulatory care sector, the problem is even more difficult. Whether Professional Standards Review Organizations

* I wish to thank Steven Snyder, M.D., San Francisco, for this suggestion.

will deal with it remains to be seen. It may have to be tackled at the medical school level, at the beginning of a physician's training, which to a large extent determines his future practice patterns. The time may well have come to seriously consider this possibility.

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Technology and the hospital

Charles A. Sanders

Introduction

Technology is commonly singled out as the major cause of rising costs in health care. Such criticism fails to consider that technology per se is but a single part of the health care system and therefore difficult to dissect away from the system itself.

Despite enormous growth in technological fields, little quantitative information is available concerning technology's cost, impact on health, or mechanism of introduction. The actors involved in the issue of technological growth include:

1. The public itself, which equates new technology with improvement in health care,
2. The federal government, whose policies in biomedical research and insurance have led to technological innovation and adoption,
3. Other third-party insurance carriers using the cost reimbursement system,
4. Private industry, with its extraordinary capacity to respond to perceived needs,
5. The individual inventor, physician innovator, or biomedical engineer,
6. Universities offering basic discoveries for subsequent application, and
7. Health care providers, whether physicians, allied health specialists, or hospitals.

This paper addresses the development, adoption, and diffusion of technology within the hospital setting. It attempts to put into perspective those forces, both intrinsic and extrinsic, that drive the system to employ technology, and offers illustrations of success and failure of the contemporary process. Current mechanisms that have an effect on the use of technology will be reviewed, and a series of potential mechanisms will be suggested that may help hospitals to adopt and manage new technology so as to bring benefits and costs into a more rational framework.

Historical perspective

Hospital costs

It is well known that both health care and hospital costs have risen at an alarming rate since the mid-1960s, quadrupling since 1964 and doubling since 1970. Expenditure for health care rose to more than $140 billion, or 8.6 percent of the Gross National Product in 1976. Of this, more than $50 billion was spent in hospitals alone. In a study of the growth of hospital costs from $13.2 to $46.6 billion between 1965 and 1975, the Social Security Administration noted that the increase had occurred at a rate of 13.5 percent annually (compounded), of which 53 percent was due to price increases, 8.7 percent reflected population growth, and 38.3 percent could be attributed to "technologic improvements." While the figure for price increases closely paralleled Consumer Price Index data for the same period, introduction of technology into health care was clearly a new and large expense.[1]

Even at the most cursory inspection, hospitals appear to face a variety of strong, conflicting, and often inappropriate incentives to adopt and utilize new technology.* New technologies have provided more efficient and accurate means of diagnosing or excluding disease, but generally have achieved palliation rather than cure. Little quantitative information is available relating the employment of technology to the extension of useful life, although the life expectancy of the general population has risen from an average of 70.3 years in 1965[2] to 72.6 years in 1975.[3] Furthermore, from 1960 to 1975, there was a decline in the infant mortality rate from 26 to 16.1 per 1,000 live births, and a drop in maternal mortality of 71 percent. In addition, the death rate in 10 of the first 15 causes of death in the United States declined. All of this suggests that we must be "doing something right."[4]

Some insight into the effect of technology can be gained by translating the experience at the Massachusetts General Hospital into cost. Although the total number of annual patient days changed little (348,000 versus 351,000) from 1965 to 1975, 1,862 new employees were added. This coincided with the introduction of 10 intensive care units spread over 97 beds with costs ranging from $200 to $425 per day (1975 dollars). New roles were needed, including medical systems analysts and programmers and a biomedical engineering department to service much of the equipment embodied in the technology. More highly skilled nursing and technical personnel were secured to administer hyperalimentation solution and to draw and analyze blood for complex new tests such as radioimmunoassays. Radiation therapists and physicists were needed to deliver sophisticated treatment to previously untreatable cancer patients, as were bioengineers capable of measuring blood flow to diseased extremities. Inhalation therapy and the acute care laboratory provide two particularly cogent examples of growth. The department of inhalation therapy increased from four technicians on a budget of $32,333 in 1959, to 70 technicians with a budget of $884,000 in 1976. An acute care laboratory established in the mid-1960s for the benefit of critically ill patients now employs 20 technicians and has an annual operating budget in excess of $800,000.

One inescapable conclusion from these data, incomplete though they may be, is that, at least in a tertiary care setting, technology can indeed be

* This conclusion and many of the ideas expressed in this paper have been derived in part from discussions of the currently sitting Institute of Medical Committee on Technology and Health Care.

"blamed" for a substantial portion of rising hospital costs. Furthermore, the major expense of the technology lies primarily in the cost of personnel and supplies to support it rather than in the acquisition cost of the equipment itself. However, the rise in cost of technology devices has not been insignificant. Although there have been substantial improvements in the capacity and sophistication of various technologies, it should be noted that between 1965 and 1977 the cost of items such as cardiac pacemakers rose from $500 to $1300, fluoroscopes with image intensification from $40,000 to $200,000, cobalt machines from $40,000 to $150,000, and computed tomography (CT) scanners from $385,000 in 1971 to nearly $700,000 in 1977.

While the foregoing commentary provides some insight into rising costs of hospital care, it does not deal with those forces either within or outside of the health care system which have created the fertile milieu wherein technology has been developed, adopted, and diffused.

The driving forces

It is impossible, in trying to evaluate the impact of technology upon health care, or more precisely, upon health, to be completely quantitative in defining those forces that have driven the health care system and hospitals to employ technology to the extent they currently do. In general, the forces are twofold, external and internal.

External forces. 1. *The public*, at least until recently, has believed that "more is better." In the mid-1960s, our national psychology was governed to a large extent by a "moon shot mentality"; there was nothing we as a people could not do, as long as we were willing to devote energy and resources to solving a problem. Improving the health of our people was no exception, and health care increasingly became defined as a "right." Little attention was given to preserving health, and the technological explosion of the late 1960s encouraged the myth that technology could rescue patients from the consequences of the major diseases afflicting the population. Accordingly, those financing research and health care services were encouraged to provide more resources, with the goal and, indeed, the expectation that such a national policy would result in better health for all. Only recently, as health care costs soar and the major diseases resist conquest, has the public begun to question whether this policy is realistic. Their question has been focused even more sharply by the realization that the nation's resources are limited, as the energy crisis demonstrates. In all, the public is concerned, although still ambivalent, about health care's commanding a major portion of their limited resources. There is still the belief that technology is a good thing; even now, more might be better. This perception remains an important force in driving the health care system, and hospitals in particular, toward developing and applying new technologies to diagnosis and therapy.

2. *The government* has reflected the public's wishes in health care in both its research policy and insurance systems.

Biomedical research, primarily embodied in the programs of the National Institutes of Health, has been a potent force in identifying and fostering new areas of investigation ranging from the most basic to applied research. As a result, investigative and clinical specialists have been developed and dispersed throughout American medical schools and hospitals. Oddly, one of the greatest accomplishments of government-funded research has been the staffing and supporting of American medical education. In addition, major advances in understanding, diagnosing, and treating disease have been achieved by technology developed through government grants and contracts. Such advances have been a major influence in shaping our current capabilities in health care; witness the development of the CT scanner, proton beam therapy, the early technology of radiology, automated systems of blood testing, computer-based drug compatibility tests, and the Medline and Medlars information systems. Although federal funding is now in large measure redirected toward categorical illnesses, it is likely that the $2 billion spent annually for biomedical research, much of it in hospitals, will continue to foster even greater utilization of technology.

Medicare and Medicaid. The legislation in 1965–66 entitling the elderly and disadvantaged to financial aid with medical expenses roughly coincided with the technological explosion in medical care. Understandably, increased demand accompanied broader insurance coverage, and increased payments directly affected the ability of hospitals to adopt and diffuse both old and new technology. Most particularly, *cost reimbursement* provided the hospitals with a guarantee against loss on a new technology, so long as the state or federal government would accept its cost into the hospital charge schedule. Thus little or no external restraint in adopting and utilizing technology was imposed on the health provider, and the technologic cycle moved onward, checked only by such restraint as was exercised by the provider.

3. *Other third-party (private) payers,* like the government, have employed a cost reimbursement system with the same disincentives to economy through conserving resources or restraining the adoption and utilization of new technology.

4. *Private industry and individual inventors* who have identified a need for a particular technology have played an important role, often in concert with potential physician or hospital users. Most of such work has been derivative of theories or prototypes developed in a medical setting, which industry, with its great developmental and fabricating capacity, is uniquely situated to capitalize upon.

5. *Universities* have also been a source of germinal discoveries which could be applied medically. In particular, those institutions with strong engineering schools have been responsible for numerous important basic advances, although the actual technology transfer has resulted from close collaboration between the university personnel and their professional

colleagues in medicine. A notable example of such collaboration was the application by researchers at Massachusetts Institute of Technology and MGH of radioactive I^{131} first to the diagnosis, and later to the treatment of thyroid disease. Nuclear medicine utilizing many isotopes is now a cornerstone of diagnosis, and, to a smaller extent, treatment of a variety of diseases. A less frequently applied technological device is the cyclotron, which is capable of treating pituitary tumors with Bragg peak radiation. Used primarily for purposes other than medicine, very expensive, and in low demand, the cyclotron has not been housed in the hospital itself.

The foregoing paragraphs suggest but by no means exhaust the range of external forces bearing upon the relationship between the hospital and technology.

Internal forces. 1. The individual physician or specialty unit has been the primary source of the development, adoption, and utilization of technological innovations within the hospital. In some instances, the path from origination to introduction into patient care has been entirely within the hospital (as in the case of radioimmunoassays for digoxin, parathormone, and thyrocalcitonin). In others, equipment or sophisticated chemical fabrication technologies requiring sizable capital expenditures have often required industrial involvement to complete the transfer and diffusion process (i.e., the Swan-Ganz flotation catheter, hemodialysis machines, circulatory assist devices, and hyperalimentation solutions). Funding for such projects has varied, although the major sources have been the federal government, and to a lesser extent, private industry and foundations.

The physician may also be requested by a particular funding source to participate ~~in~~ the development or evaluation of a technology which ultimately may help in patient care, as in the case of government and private industrial contracts to conduct animal and human testing of drugs and medical devices.

2. *The hospital* has seldom been the prime mover in identifying the need for new technology, seldom considered itself responsible for innovation or even for monitoring the introduction of technology into patient care, beyond assuring patient safety and establishing programs ~~which~~ are economically viable. In the case of safety, the malpractice crisis and the requirement that standing committees on human subjects review research proposals have heightened hospitals' awareness of their responsibility. However, because of the numerous pathways by which new technology can be introduced into the patient care setting, these concerns have not provided an overall screening method. Assuming that safety standards or risk-benefit ratios were acceptable, the major force in deciding whether a new technology would be introduced has in fact been whether third-party carriers would reimburse the hospital at a level sufficient to sustain the technology. In the setting of cost reimbursement, there has been, and is, little incentive for the hospital to view the benefit-cost influence of the technology on individual diseases, or to examine the new technology in the context of the total diagnostic and therapeutic capability of the institu-

tion. Moreover, no incentive has existed for hospitals to consider using similar and underutilized services in other nearby institutions. Their failure to do so has prompted the charges that hospitals are insensitive to cost, promote needless duplication of services, and mindlessly pursue their own parochial interests. To be balanced against such charges are considerations such as transport of patients, the type of hospital involved (full service versus community), the actual projected need for the technology, and, as a corollary to the last, the fact that some duplication within the system is necessary when the demand supports approximately full utilization of the technology.

Thus the hospital to date has been largely passive in the introduction of technology. Although it has not had to be so, the pressures generated from within by the physician inventor and by practitioners wishing to use the technology, even on an initial trial basis, can be extraordinarily powerful. In fact, with a permissive reimbursement system it has been, and is, easier, and sometimes wiser, to adopt promising technology even before its ultimate role in patient care is certain, than to refuse an opportunity to explore its potential benefits. Today's hospital faces a myriad of incentives to utilize technology and disincentives to constrain it.

Illustrative case studies

Before citing two case studies of the development, adoption, utilization and diffusion of technologies in medicine, let me emphasize that these examples illustrate that technology and its place in medicine are moving continuously. We are forced to make judgments about technology with imperfect methodology and data and in a time of increasingly limited resources, while simultaneously we have a national commitment to improve the health of our citizens and protect them from potentially dangerous chemicals, energy sources, medical technologies, etc.

Still, we should not forget that medical advances such as digitalis, penicillin, insulin, smallpox vaccination, vitamin B12 for treating pernicious anemia, and numerous medical devices have been introduced without clinical trials of any magnitude and have been accepted and retained at least in principle because of their obvious therapeutic benefits. In other instances, technologies, particularly in the fields of antibiotic and cancer chemotherapy and medical devices, have followed the same abbreviated path to clinical application and have been discarded, usually within a short period of time, when they were found ineffective or actually harmful. In the latter instance, most such trials have been carried out in patients for whom there was no satisfactory therapeutic alternative.

The following two examples are illustrative of successful and failed technologies and, although oriented toward the field of cardiology, serve as an analogue to many examples that could be cited in this or any other medical specialty.

Coronary arteriography and bypass surgery. Selective coronary arteriography exemplifies a diagnostic technology which had to wait nearly a decade for a therapy that could palliate the disease it was clearly capable of diagnosing: coronary artery disease. Coronary angiography was introduced in 1958 by Dr. Mason Sones of the Cleveland Clinic,[5] and several thousand angiograms were performed, primarily in his laboratory and almost exclusively for diagnostic purposes. Only a few patients were referred for surgery, because the only technique potentially capable of improving myocardial blood supply was the implantation of one or both internal mammary arteries into the myocardium (Vineberg procedure), with the expectation that the implanted vessels over time would establish connections with existing coronary vessels, thus improving blood supply.[6] That procedure, although introduced in 1949, was of dubious value and never accepted widely. Probably fewer than 200 such operations were done between 1949 and 1967.

Nonetheless, coronary angiography flourished in the Sones laboratory despite the lack of an accepted therapy, despite the high cost of radiographic equipment, and despite the relatively high doses of radiation. The multiple reasons for acceptance of what was essentially a diagnostic procedure included its apparent ability to exclude coronary disease as a cause of dibilitating chest pain, the precision with which a diagnosis could be established, and the willingness of the individual patient and some third parties to bear the expense of the procedure.

With the introduction of the saphenous vein bypass graft procedure in 1967,[7] a therapeutic modality became available which apparently provided immediate improvement of blood supply to an undernourished myocardium. Although it required vast technologic support, its simplicity and logic were powerful forces in its being accepted widely and rapidly as therapy for this country's leading cause of death due to medical disease. The rest is history known to all in the field. Open heart surgery, previously limited to valve replacement and repair of congenital heart defects, initiated a new era. Currently, it is estimated that more than 50,000 bypass operations are done annually at a cost in excess of $10,000 per operation. The approach was propelled forward by the medical instinct for effective procedure and the strong emotion generated by the consequences of coronary disease, and in the beginning few quantitative questions were asked about the effectiveness of the surgery as it related to morbidity and mortality. To be sure, trial and observation have disclosed that some patients were not benefited, because their disease had progressed to the point where the heart was irreparably damaged and restoration of blood flow could not improve it. Such patients are now viewed as potential candidates for cardiac transplantation, if and when the immunologic problems surrounding that procedure can be solved. Yet, the vast majority of patients with symptomatic coronary artery disease have been viewed as candidaes for the bypass procedure. And in some centers it is alleged that patients with asymptomatic but apparently "life threatening" lesions should also be bypassed.

Despite the enormous commitment of resources to this technology, which in fact is a family of technologies including cardiac catheterization, radiology, cardiopulmonary bypass machines, blood banking, etc., it is only now that data are emerging that purport to demonstrate that the operation relieves symptoms and prolongs life. Such data are usually retrospective in nature, not subject to double blind or control techniques, and in many instances, ignore the natural history of the disease. To keep things in perspective, it is probably too late to carry out classical statistical studies, in part due to our population's mobility and freedom of choice in seeking therapy. Furthermore, if the procedure were a failure, or largely so, the evidence already would have accumulated to indicate as much, and the procedure would have been discarded as other ineffective procedures have been, such as the Vineberg operation, pericardiolysis, and omentopexy.

Comment: The study illustrates the preoccupation our society has with technology, particularly when, like coronary angiography, it has a diagnostically precise capability, or appears to offer a logical and simple therapy for a severe, ubiquitous disease. One wonders what the course of events would have been had the medical profession urged more restraint in the introduction of this technology and set up a method to evaluate its effectiveness statistically. Could medicine have resisted the public outcry, emotional though it may have been, which might have accompanied knowledge of the availability of a procedure which is superficially so attractive? Could the third parties who have paid for these technologies almost from their beginning have withstood such pressure? The question is moot but provocative and, if considered, should be examined in light of the times in which the developments took place.

Prosthetic devices in cardiology. With the increased knowledge and interest of the engineer and physicist in biologic systems, activity in developing prosthetic devices for all fields of medicine has burgeoned. The field of cardiology has been exceptionally active, since in many ways the principles of hydraulic engineering are applicable to the cardiovascular system. The main problem in this rapidly expanding area has been to develop a prosthetic material having a surface which is biologically compatible with blood over an extended period of time, and also having sufficient endurance for the device to function effectively and repetitively in the continuous trauma of a pulsating system. Despite these difficulties, Hufnagel in the 1950s devised and inserted a plastic valve into the descending portion of the thoracic aorta in patients with severe aortic insufficiency.[8] This technology antedated the development of the cardiopulmonary bypass machine and admittedly was a desperate attempt to palliate a disease which had reached its end stages and for which there was no alternative therapy. Little was understood at that time about the biologic interaction of blood and foreign substances. Placement of the valve in the descending aorta only partially relieved the work load on the left ventricle, since the aortic valve itself continued to be incompetent and the blood ejected into the upper portions of the body would continue to regurgitate into the left ventricle. The history of the Hufnagel valve was short, and in retrospect, predictable. The patient's symptoms were relieved only partially, although for a time the cardiac condition was more manageable clinically with drug therapy.

However, the major limiting factor was the incompatibility of the valve itself with the blood. The resulting clot formation, embolization to areas distal to the placement of the valve, and complete obstruction of the valve by clotting created insurmountable obstacles. Hence, the valve was never widely accepted, although a few patients were substantially benefited, albeit for a short time. Thus this technology, which was created and introduced by an imaginative physician, did not diffuse throughout the cardiovascular field, solely because of its soon obvious limitations and not because of safety policies imposed by the government or policies of reimbursement by third-party insurance carriers.

In 1961, the modern era of cardiac-valve prostheses began with the collaboration of a surgeon, Dr. Albert Starr, and an engineer, Lowell Edwards, who developed the Starr-Edwards valve to replace diseased cardiac valves.[9] This approach was made possible by the availability of effective cardiopulmonary bypass support. It is interesting that the Starr-Edwards prosthesis, still extant, did not diffuse widely until the clinical trials conducted by Starr himself in a number of patients with various types of mitral and aortic valve disease indicated that the valve was an effective therapy for the diseases in which it was employed. Although the third-party payers were not reluctant to reimburse for this procedure even in its early stages of development, the natural caution of the medical profession toward what was then radical therapy delayed the widespread use of these devices until their clinical worth could be proven. To some extent, however, the acceptance was delayed also because of the relatively few centers capable of providing the skilled personnel and technology to support the invention. However, as the worth of the valve became proven, there was a marked growth in the number of cardiovascular pump teams throughout the country primarily devoted to applying this technology. In retrospect, the proliferation of such teams was excessive but responsive to a number of factors, including public demand, the desire of physicians and hospitals to provide this capacity in their facilities, and the willingness of third parties to reimburse for the procedure.

Nonetheless, it should be emphasized that the technology was applied for the most part to patients for whom no effective alternative source of treatment was available. The benefits of drug therapy had been exhausted and, at least at first, valve replacement was reserved for the most severe cases, a practice which has continued to the present in the application of radical technologies. As experience demonstrating its effectiveness increased, valve replacement was extended to patients who were less severely affected by their disease. Thus the major issue of when such palliative therapy should be employed was and still remains one of judgment.

As might be predicted, valve replacement is not without severe complications in some patients. These include unseating of the prosthesis, embolism from clots forming on the prosthesis, hemolysis of blood due to the excessive shear forces on the formed elements of the blood in contact with a foreign substance, and actual degeneration of the poppet within the valve despite extensive endurance testing in the engineering laboratory. In an effort to build a device free of such complications, other valve prostheses have been devised by individual physicians, sometimes in collaboration with hydraulic engineers. In their early stages, virtually all of these employed foreign materials which during the test of time in patients have been found to produce the same problems of the Starr-Edwards valve, and usually with an even greater frequency. Thus these devices now in large measure have been discarded. The Starr-Edwards valve itself has continued to undergo development and at present is the standard technology for valve replacement, since the refinements have led to a progressive diminution in the frequency of the previously described complications.

Nonetheless, because valve replacement patients require long-term anticoagulation, not without complication itself, there has been a continuing search for a better prosthesis. One of the areas that initially appeared promising was the transplantation, primarily in the aortic area, of human valves obtained from patients who had died from other causes. However, this technique has suffered from a number of problems involving availability, preservation, technical difficulties in insertion, and fatigue of the valve after it has been in place for varying lengths of time. Currently, the major focus in new prostheses is on the potential of applying allografts, usually derived from the pig because its tissues appear compatible with those of the human, apparently will not require long-term anticoagulation of the patient, and may not be subject to the complications encountered with the Starr-Edwards valve. The driving force in development of this new technology is no longer the individual physician, or physician and engineer in informal collaboration, but a whole cohort, including physician, engineer, industry, and government. A major facilitating factor in testing this new technology in the human has been the willingness of third-party payers to reimburse for the procedures, even though the technology still must be considered in its experimental phase.

Comment: Beginning with the Hufnagel valve, there has never been a standard clinical trial to prove the effectiveness of any given valve replacement prosthesis. The lack of an effective therapy in desperate clinical situations gave rise to the development of this field, and the policy of third-party carriers of reimbursing for the procedures facilitated its adoption and diffusion throughout the hospital system. Ineffective prostheses have been discarded primarily because they failed to meet the standards of individual physician researchers. In addition, the indications and hence the utilization of these devices in the human have been left to the judgment of individual cardiovascular teams, whose processes of evaluation and review may vary considerably from institution to institution. Finally, the decision to introduce such technology has rested largely with the physician, and hospitals have played little, if any, role of this decision making process. However, some hospitals have actually sought this capability to maintain their position of eminence within a community. To the extent that this has been the case, unnecessary duplication of expensive services may have resulted. Regardless of the mechanism by which the decision has been reached to adopt this or any other type of technology, the hospital has had to provide many supporting services whose cost in terms of personnel, space, and equipment has not been counted in when the major technology itself was adopted. This may explain, at least in some instances, why cardiovascular teams, after enjoying an initial period of support, have been found to be inappropriately placed, that is, placed in institutions whose patient volume is not adequate to support the effort. The cardiovascular field is not alone in this situation.

Control of technology in hospitals

There are two major reasons to consider the question of control of technology in hospitals: (1) the high cost of health care, and in particular hospital care; and (2) concern about protecting the public from the introduction of technology that may be of minimal effectiveness, or that might prove harmful.

The following comments will be directed toward existing control mechanisms and will suggest some new mechanisms of potential value.

Current mechanisms

Determination-of-Need and P.L. 93-641. At present, 33 states and the District of Columbia have operative Determination-of-Need laws, although these vary in scope and in particular as to whether or not doctors' offices are included. Public Law 93-641 mandates that a Determination-of-Need law be in place in every state by 1980, but it does not require that the law extend to doctors' offices.

Although this mechanism is attractive in theory, experience to date suggests that it is extremely difficult to implement. Effective planning is limited by the amount of data available upon which to base decisions. Much decision making has occurred in an atmosphere of crisis generated by a request from specific providers to adopt new technologies or replace old facilities. Faced with such crises, decision making authorities have been unable to devote their attention to developing a methodology that addresses the structuring of a health system which makes facilities and their technology available on an equitable basis. Their power has been limited by their inability to have a marked effect upon existing facilities. However, it is conceivable, and even likely, that in the absence of specific authorization, those administering Determination-of-Need laws will resort to the indirect method of closing hospitals by denying applications to upgrade old facilities which have been cited for failure to conform to current life safety codes. While such practice constitutes blatant abuse of the intent of the Determination-of-Need law by employing methodologies outside the scope of the law, it nonetheless is a way to "game" the system in order to make it conform to the wishes of the regulators. Were such regulators possessed of the necessary data and wisdom on which to base decisions, the means they used might be condoned as justified by the ends. Unfortunately, the professionalism currently resident in Determination-of-Need authorities is not such that the public can be assured that the laws will be directly or indirectly applied in an equitable fashion. Furthermore, Determination-of-Need pertains only to large technologies whose capital costs exceed $100,000 to $150,000; thus, a significant amount of new technology could be introduced which would fall below the threshold for review but would increase the costs of medical care as much as, if not more than, certain technology over which the law has jurisdiction.

The addition under Public Law 93-641 of Health Systems Agencies and State Health Coordinating Councils to work with the Determination-of-Need process appears to address some of the above questions. Again, however, the law is extremely complex and idealistic, for it is based on two assumptions. It assumes that the requisite amount of data can be collected upon which to make decisions about the health care system, and that the professionalism required for such decision making can be developed within public bodies which are theoretically representative of the populace. At this time, it is difficult to point to a health systems agency that possesses the necessary planning expertise and can be considered truly representative. Indeed, the process to date has not resulted in attracting those elements of community leadership that would give one confidence that the needs of the public at large rather than those of the vested interests, be they rich or poor, had been taken into consideration. Furthermore, these agencies have failed to link their efforts effectively with the Determination-of-Need process. They exhibit operational inefficiencies and lack of continuity in defining and pursuing the mandated goals in health planning. These same criticisms have been directed at hospitals, which specifically have been criticized for failing to cooperate with one another to ensure that overbedding and excessive duplication of services among hospitals do not exist in any given area. There is a clear question as to whether or not the health systems agency and Determination-of-Need process can or will be able to develop a coherent health system that is better than the current "system." Theoretically, the answer should be a resounding "yes," but in practice, the performance of this public process has failed to inspire much confidence.

Some success might be achieved if, at least from a procedural point of view, the agencies involved in public planning could respond in a timely manner to organizations requesting Determination-of-Need. Although agency practices and administration of Determination-of-Need laws vary from state to state, the time required to make decisions is extraordinarily long. Facilities or technologies may undergo such extended review that the cost of the capital expenditure can increase substantially simply because of delays in processing the application.

If the regulatory process could be efficiently administered, some yardstick to measure its performance could be developed. The current practice unfortunately tends to deny or delay all proposals for an unconscionably long period of time. At the Massachusetts General Hospital, for example, an ambulatory care center has been under consideration for nearly three years. During this time the costs of construction and capital equipment have risen by more than 25 percent, excluding, of course, the incremental cost personnel committed to seeing the project through to conclusion, whether it be a positive or negative action on the part of the public bodies. Similarly, the Affiliated Hospitals Center in Boston spent more than five years in obtaining approval for a facility which finally contained 100 fewer beds than were proposed but whose inflationary cost had risen more than two and a half times during the interim. Some would argue, and not without merit, that while the ultimate result of such a process was a better hospital, the real question is whether or not it was sufficiently "better" to justify an expenditure of $100 million rather than $40 million. Many similar problems could be cited which have arisen in the process of implementing Determination-of-Need laws.

Cost control commissions. A number of states have established cost control commissions in an effort to contain the rate of rise of hospital costs, of which technology is thought to be a significant component. These include Massachusetts, Connecticut, Maryland, and Washington. Although the method of operation may vary from state to state, each commission exerts considerable authority over the degree to which hospitals may raise charges to cover the costs of services provided. Such commissions theoretically are attractive from a cost containment point of view, since they could be useful in controlling the proliferation of technology within the hospital, but to date they have lacked the expertise or data base on which to make judgments regarding the role of a hospital in a particular area. Like the Health Systems Agency and the State Health Coordinating Council, these commissions are capable of addressing only a portion of the problem of developing a health care system, namely, cost. Again, if commission activities in approving or disapproving charges could be linked to an effective planning process, their impact would be enhanced greatly. Such a linkage has not developed to date. The performance of the commissions must be judged against their ability to contain costs, as compared to cost containment in other states without similar regulatory processes. When that comparison is made, commission performance is not impressive. A 1976 study covering 18 states attempted to ascertain for the Federation of American Hospitals the effect of rate regulation on hospital expenditures and revenues. This study revealed little, if any, impact attributable to the presence or absence of mandatory rate regulation and a 1-2 percent better performance in states with voluntary rate regulation.[10]

The stock answer to why the performance of cost control commissions has not been better is that such commissions are still evolutionary and their potential remains to be realized. While it is impossible to argue with such a statement, the approach appears far from being a panacea. It is difficult to see in a free society how the adversary relationship commonly resulting from the actions of such commissions will in fact realize the desired goal without creating chaos, or, at the very least, inertia, in a system which is constantly in motion, and whose major actors are committed, at least superficially, to improving the quality of care delivered to our citizens. Such adversary relationships do *not* provide incentives for better performance, but create a mindset among the regulated that is geared toward protecting what they have, rather than toward the economic wisdom of investigating how they might achieve their goal through cooperation and planning.

FDA and medical devices legislation. The key federal instruments addressing the adoption and diffusion of technology at this time are the regulations of the Food and Drug Administration (FDA) and the recently enacted Medical Devices legislation. The role of the FDA is to protect the public safety and to keep off the market those drugs that are of no use or of marginal utility in the field where they are applied. The scale of their task is awesome, and its stringency is such that it is little wonder that the United States has fallen far behind in the development of new drug technology, ranking behind a number of European countries as well as Japan. The standards to which domestic industry are held in developing new drug technology are so severe that there is an inordinately long lead time, ranging from months to years, before a new drug originating in the United States can be sold on the open market. In our zeal to protect the public safety, we have forced the FDA to adopt standards which have spawned a federal bureaucracy incapable of timely response to the enormous capacity of American industry to produce drugs potentially useful for the treatment of a number of common diseases. To be sure, the introduction of drugs onto the open market should not be a completely unfettered process, but the standards to which American industry are held at the present time are enervating and wasteful of resources. This policy, if continued, may in the long run be detrimental to the American people.

The Medical Devices legislation, also administered by the FDA, has the laudable goal of ensuring that no new devices will be accepted for the open market until they are appropriately tested. The legislation divides devices into several categories, with the most stringent standards applied to those inserted into the human body. Such legislation in many ways is overdue, but it is crucial that the standards set in the implementing regulations be reasonable and not unduly idealistic. What is to be measured is the risk-benefit ratio of such devices when compared with the alternatives; in some cases there are none. The natural tendency in administering a federal law is to "play it safe." If bad results occur in a few cases, the attendant sensationalism distorts the actual contribution of the technology. It can only be hoped that in the application of the law to medical devices an effective mechanism for initial testing, and, equally important, a means for continuing evaluation will be devised, with the understanding that if a device is found wanting after preliminary testing, it may have to be removed from the market. One possible mechanism for preliminary evaluation might include convening a national review panel composed of experts on the subject to develop a research protocol to be carried out in a few selected centers, initially in animals and, if apparently successful, later in humans. The time frame for preliminary evaluation would, of course, depend upon the type of device under study. Ongoing evaluation could be the responsibility of a separate peer review panel convened under FDA auspices. To ensure objectivity of evaluation once introduction and diffusion have taken place, such panels should be composed of individuals not participating in the original decision to place the device on the open market. A similar process might be employed for the drug field as well, that is, initial confirmation, by a panel, of animal testing carried out by the industrial laboratory followed by clinical trials in a few designated medical centers throughout the country. Whether the FDA can or should bear such heavy responsibility for testing and standards remains unresolved.

Third-party insurance carriers. Currently, third-party carriers play only an indirect role in the evaluation and acceptance of technology into the medical field. Where prospective rate setting is the major form of reimbursement—that is, a rate of reimbursement is provided to the hospital based on some standard of case-mix which considers the types of services provided, the hospital must determine the relative importance of various technologies it wishes to support in order to balance its budget. In such a milieu any introduction of new technology must be within the fiscal constraints of the reimbursement limitations imposed by the third-party carriers. Although prospective rate setting has been adopted for Medicaid in numerous states, the existence of pluralistic forms of reimbursement in a state ensures that third parties are not a great deterrent to the introduction of new technology. Cost reimbursement remains the mechanism by which most hospitals are funded for the services they provide. This area is ripe for extensive exploration.

Potential mechanisms

Before discussing the discrete mechanisms by which technology is introduced and ultimately controlled, it should be emphasized that the most effective policy will be one that alters the system by retaining incentives for the individuals who control the technology. Two mechanisms, prospective reimbursement and utilization review, appear to hold considerable promise. However, to attain them requires, first, a major change in policies governing reimbursement, and, second, development of a utilization review that includes ancillary services rather than merely utilization of beds, as originally mandated by the Medicare Act of 1965.

Prospective reimbursement. Prospective reimbursement has the potential of bringing together all the decision makers in the hospital to discuss the adoption and use of a technology. To accomplish this requires behavioral modification in a system where the individual physician entrepreneur has long been the prime actor in the utilization of new or old technology, while bearing no risk. And such behavioral modification cannot be accomplished so long as a cost reimbursement policy exists, i.e., so long as the hospital can routinely pass the cost of any new or existing and possibly overutilized technology along to a third-party payer. Clearly, the third party is not in a position to make decisions regarding the importance of new technology, and the federal government, through the FDA or other agencies, is not really able to establish the efficacy of a particular technology in a highly specialized hospital. A prospective rate setting system that recognizes the individual characteristics of a hospital and provides a rate that adequately compensates for the services provided, is a powerful motivating force toward intra-institutional decision making. Such decision making not only has the advantage of imposing the responsibility for the introduction of new technology upon those most qualified to evaluate it, but also has the decided benefit of promoting an institutional awareness of the utilization that exists already either in the hospital or in neighboring institutions. Inter-institutional cooperation is thus facilitated, and a genuine will to cooperate for the common good is fostered.

Although prospective rate setting is not the ultimate answer to the containment of medical costs, be it applied to technology or to the utilization of hospital beds, it does vest the decision making in those most qualified and relegates the regulators to a role they can more naturally assume, that is, ensuring compliance with a system which has been developed. The difficulty in setting a prospective rate rests in devising a formula that recognizes differences among institutions (i.e., the difference in costs of providing services in a tertiary care institution and providing them in a community hospital). Some have proposed that a case-mix approach be employed; others have contended that such a formula is susceptible to manipulation on the part of the provider. Undoubtedly, there is truth in both arguments, but the concept of prospective budgeting is sound, and devising a methodology for it should not prove an insurmountable obstacle. It offers an opportunity to achieve a number of goals common to the provider, the payer, and the regulator.

Utilization review. Until now the concept of utilization review has been confined to the issue of bed occupancy. It has not been extended to the monitoring of ancillary services employed in the diagnosis and treatment of specific illnesses. As a result of the extraordinary demand for medical services generated by Medicare and Medicaid entitlement and by other third-party insurance carriers, as well as by the availability of extensive technological innovations over the past 12 years, it is not surprising that hospitals have budgeted for steadily increasing laboratory utilization rates. The major question, of course, is whether or not such technologies have been appropriately utilized in diagnosis or therapy carried out in the most effective manner. It seems likely that overutilization of available technologies occurs. We do not know this to be a fact, but because of our inability to define quality of care and also because of the malpractice crisis, there is clearly a latent, if not actual, tendency to use available technology without necessarily considering its real contribution to solving the problems of the patient.

Considerable savings might be achieved if an effective utilization review program relating to quality of care in a specific illness could be developed, either through the mandated Professional Standards Review Organization mechanisms or through the initiative of third-party payers. The difficulty in defining "quality of care" is enormous, in that quality acceptable in one setting might be found wanting by the criteria of another. Nonetheless, it is imperative that our society and the medical profession, in particular, agree upon some ground rules which will of course require refinement through time. It is likely that if the problem of quality and utilization can be addressed in a meaningful way, money previously expended in applying existing technologies for marginal indications might be freed up. In the best of all worlds, it could then be applied to the development and evolution of new technologies to supplant the old.

Limitation of capital. A simple but rigid way of controlling technologies in the hospitals or in other health care settings would be to limit the spending for new technology and facilities in a given geographic area. This proposal is found in the current Carter bill. While it might be effective in saving money, it might not recognize distinct and important regional characteristics reflected by the types of hospital and service provided. In particular, hospitals with a high density of tertiary care might be ill served by such a policy, since they are the largest and most sophisticated users of both new and old technology. Furthermore, the policy would not respect the pluralistic nature of the American free enterprise system, particularly the freedom of choice which patients enjoy, and in all likelihood will want to maintain, to determine where they will seek medical care and how much they will pay for it. These comments are not to be confused with issues of equity relating to providing people with access to a reasonable standard of health care wherever they live. On the other hand, it is the obligation, and indeed the strength, of our system to promote the capacity of institutions with special expertise to provide sophisticated services of proven value. If a formula is applied rigidly and does not consider the special characteristics of institutions in our country, then the leavening process will inevitably result in mediocrity within the system. Excellence may be sacrificed unnecessarily in the name of cost containment and accessibility. The latter, while important, is a separate end attainable through other mechanisms, and it should not be allowed to detract from a greater issue. Mediocrity has never been the American goal, and it would be sad indeed were it allowed to assume that position in our health care system.

Summary

The American health care system, in particular its hospitals, has come to that point in its history where care must be observed both in the introduction of new technology and in the use of the old. To achieve this, a behavioral modification on the part of hospitals, physicians, and the public must be brought about. In the view of the author, such a modification is best accomplished by promoting incentives within the system, rather than by the imposition of stringent outside regulations relegating the provider and the regulator to adversary positions. The solution will be complicated and multifaceted, but achievable so long as the incentive principle is preserved, and it is recognized that the current situation was reached not within the span of days or months but over several decades. Time and patience will be needed if we are to achieve the goals we commonly seek and maintain the unique capacity that has made the American medical system the world's laboratory for technological innovation. To allow providers to manage available resources under regulatory guidelines would retain incentives and potential for growth and innovation. Alternatively, if the decision making power over the delivery of health care and the adoption and diffusion of new technology is placed entirely within the regulatory bodies, it is doubtful that the system that has made this country preeminent in many areas of health care will be preserved.

There are admittedly many problems remaining to be solved in the areas of accessibility to health care for all of our population; containment of health care costs, which have been rising at an inordinate rate, and assurance of the quality of care which is delivered. These questions are not insoluble nor are they entirely dissociated from those that relate to technology. Nonetheless, they can be solved at least partially if the problem is approached on a systems or institutional basis rather than by looking at each problem as if it were separate and distinct.

Conclusion

This paper might be most appropriately concluded with a series of questions:

1. Has the evolution of technology in hospitals been the result of the parochial interests of physicians or hospitals, or has it been due largely to a health system committed to conquering or palliating the major diseases afflicting our population, combined with a reimbursement system which has not been conducive to critical analysis of the cost of introducing and continuing to use new technology?

2. Recognizing that technological innovations have had varying success and in some instances clearly failed, is it surprising that in a country blessed with plentiful resources the evolution of technology has fostered whole new industries and professions dedicated to the preservation of life?

3. In our frustration over rising costs in a time of limited resources, should we turn the control of a health care system with its admitted faults over to government regulation, which in other countries has failed to produce the type of cost control and quality of care that the American public has come to expect and the medical profession wants to provide?

4. Is there a health care crisis in the ultimate sense that our citizens are unable to find the health care they require? Or, is there a crisis in the sense that *some* groups do not have access to the system that they require?

5. Will the provision of a health care system that is accessible to all be the answer to the problems of health? Or, does the answer reside primarily

in improving the socioeconomic status of all Americans, in educating our population on preserving health, and in continuing our commitment to research aimed at discovering the causes and therapy for major diseases affecting the population?

6. Is it realistic to expect that as our population grows older and therefore more susceptible to multiple diseases, that the important role of palliative medicine will be diminished? Or, is the major question really one which addresses a balance among preventive, early detection, and therapeutic technologies?

7. Finally, is it realistic to expect that the total cost of maintaining health and providing health care is going to remain stable or diminish?

As we ponder these questions, there are no clear answers. Our problems relate to frustration in the face of complex and sensitive issues of limited resources and the preservation of meaningful life. They must be addressed, at best in an objective, constructive atmosphere, by persons dedicated to the maintenance of high-quality care and compassionate cost containment, not governed by the mindless question of how much health care can be bought for a dollar.

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Anticipating the costs and benefits of new technology: A typology for policy

Gerald Rosenthal

Introduction

It has become fashionable recently to make cost containment the major focus of public policy in health care. Emphasis is given in public discussion to the need for "controlling the rising costs of health care" before efforts to improve the performance of the system can be undertaken. While this position receives widespread support, both the views as to cause and the prescriptions as to response display a wide range of opinion.

Two general perceptions emerge. First, in contrast with discussions of health care policy of the 1960s, which tended to emphasize almost entirely the potential benefits to be derived from any change in the health care system, there is now increased attention directed at the costs likely to be associated with the change. Second, there is a strong desire to find a scapegoat for rising costs and focus the cost containment on it, rather than to recognize either the complexity of the task or its wider effects on the health care system.

These perceptions have taken root in an environment where there is increasing concerned awareness that much of what is done in the name of "good medical care" has little, perhaps no, positive impact on health status and, under some circumstances, may actually produce negative results in the patient. The effect on medical demand wrought by increase in the prevalence of chronic disease and the related need for long-term care have tended to reduce our belief in the capacity of "science" to *cure*, since much of what is done in the health care system is life-supportive without any expectation of preventing or eliminating the "disease." The growing proportion of resources being devoted to the care of the elderly and terminally ill only reinforces this view.

It is not surprising that these circumstances have generated a growing skepticism as to the wisdom of continuing to encourage the unfettered development and proliferation of new medical technology. For some, the pendulum of support has swung completely from a position that the *benefits* from technology are sufficient to justify any *costs*, to a position that technology generates so many *costs* as to negate any *benefits!*

One of the purposes of this meeting must be to identify the degree to which specific policies could be implemented to moderate the technology-generated pressure on costs, while not forgoing all of the benefits which can emanate from a responsible technology development strategy. Any policies directed at making adoption of a new technology less easy must incorporate means to assure consideration of both costs and benefits in ways not encouraged in the current structure of the health care system. Clearly, all new technology is not bad, and a critical element of technology policy will be the degree to which it explicitly addresses options for development, distribution, and scale of medical care technologies. To the extent that distinctions can be made among types of technology on the basis of expected costs and benefits, the task of developing policy in this sensitive area might be made more manageable. This paper addresses that goal.

A typology of medical technologies

In a real sense, all changes in the way medical care services are produced and distributed are changes in technology (with a small t). However, the current discussion is directed at a more limited category, often called "hard" technologies. These are typically distinguished by costly new equipment and major capital expenditures necessitated by their adoption. But even limiting the discussion to "hard" technology, it is difficult to address the "problems" of technology in generic terms or to develop policies which can have a positive impact across the wide range subsumed by the term.

The need for differentiation among types of technologies is increasingly acknowledged. When Lewis Thomas used the phrase "half-way technologies" to describe an area of modern medical care, he was referring to the increasing tehnical resources being devoted to care, the purpose of which is not to cure but rather to manage illness, often when there are no immediate expectations of cure. While the Quinlan type of case is one extreme example, others are more common, such as renal dialysis. Implicit in Dr. Thomas' categorization of "half-way technology" is a statement about expected future costs and benefits. Such technologies, as he describes them, are associated with relatively high costs for an extended period of time (limited typically by mortality) without any direct expectation of cure. This is not to say that no benefits are generated. Rather, such benefits are less apparent than cure and more difficult to assess. The "half-way technologies" contrast with the simpler, cure-focused view of homeostatic medicine that guided earlier investments in developing technology.

The contrast that Dr. Thomas points out is important; it makes clear the implications of differentiating among types of technologies in terms of expected future benefits as well as of the timestream of costs. Those benefits are first delimited by the nature of the medical circumstances for which the technology is being developed. This argues for differentiating among technologies by their medical objectives. Following that strategy, it is possible to expand the set of categories in ways that provide more insight into the process of developing and applying new technology.

The following table presents such a typology of medical technologies with some examples.

Categories 2–4 represent a continuum rather than discrete clusters. The pacemaker could be considered either an illness management technology or a cure technology, while the iron lung fits either survival or illness man-

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Table 1
A typology of medical technologies

Type	*Example(s)*
Diagnostic	CAT scanner Fetal monitor Computerized electrocardiography Automated clinical labs
Survival	Intensive care unit Cardiopulmonary resuscitation Iron lung
Illness management	Renal dialysis Pacemaker
Cure	Hip joint replacement Organ transplantation
Prevention	Pediatric orthopedic repair Diet control for phenylketonuria Vaccines for immunization
System management	Medical information systems Telemedicine

agement, depending on one's view of its medical impact on the patient. For our purposes, precision at the boundary is less important than well defined central tendencies. Although not, strictly speaking, medical technologies, system management technologies are included for the sake of completeness. The discussion that follows attempts to identify for each category issues that would need to be addressed in any policies that were designed to influence the cost impacts of new technology by limiting its application.

Diagnostic technologies

Much of the recent discussion of medical technology and its impact on costs has been stimulated by the rapid spread of a major new diagnostic tool, the CAT scanner.

Two specific types of diagnostic technologies can be identified. The first is a new way of processing existing tests, such as computer interpretation of X-ray film and electrocardiograms. In this type, benefits come from either unit cost reduction or increased precision. These new technologies tend to be used about as much as the ones they replace *unless cost reductions are sufficient to encourage an expanded use*, as in the case of the automated clinical laboratory.

The second type is a new diagnostic test, such as the CAT scan and ultrasound monitoring. In this case, the potential application levels are less clear. If the technology is specifically focused on a particular disease with clear indicating symptoms and known incidence, it may be possible to anticipate the scale of application with some confidence. More typically, however, new diagnostic tools create opportunities for application as they become more available, in part because they may be permitted without the requirement of a prior "probable" diagnosis. This is most likely to occur if they substitute noninvasive procedures for invasive ones, thereby reducing the apparent risk to the patient. The recent CAT scanner experience probably reflects influences little different, albeit considerably more rapid, than those influencing the growth of radiology generally; it may well be repeated with the development of ultrasound-based technologies. The huge multiplication of tests for suspected brain tumors in institutions that had acquired CAT scanners does not suggest an incipient epidemic, but rather, a response to test availability, reduced patient risk, and reimbursement policies.

Other factors also tend to expand the application of diagnostic technologies. Malpractice considerations and the practice of "defensive medicine" make the cost of not giving a test potentially higher than that for giving it. If the risk of testing is reduced by the new technology, the pressure to use the innovation will be even stronger. Any policy designed to limit application will need to deal directly with this pressure.

Many of the benefits to be derived from diagnostic technologies depend on the degree to which the medical care system can respond to improved diagnosis with an improved outcome. Therefore, all applications of a given technology are not likely to generate equal benefits. Policies limiting the availability of a diagnostic technology need to incorporate some means for directing it toward the applications that generate higher benefits. Such a policy can take many forms, including limiting reimbursement to particular sets of circumstances where indicators for the procedure can be specified, or requiring multi-institutional access to a technology approved for installing in a single institution under Certificate-of-Need programs, thereby placing the allocation responsibility on the set of institutions that share access.

The application of a diagnostic tool can have significant secondary effects. An improved capacity to diagnose often serves to suggest outcome-improving technologies and to focus the necessary research and development effort.

The responsiveness of new diagnostic tools and procedures to all these stimuli makes their cost impact particularly difficult to control. In addition, their use is difficult, if not impossible, to limit on medical grounds. There is considerable evidence that high capital costs alone represent no significant barrier, since the volume of use that can be medically legitimized (as with the CAT scanner) allows rapid recovery of costs.

The expanded use of a new test device caused by all these factors creates another problem. It generates second-order expenditures for followup of false positives, corroboration of indicative but inconclusive results, and the hospitalization and physician visits that may accompany the diagnostic process. The impact on cost of these secondary effects may be more significant for the automated clinical lab than for the CAT scanner, though the scanner's high capital costs tend to capture the attention. The point is that *all* widely applicable diagnostic technologies generate costs beyond those strictly related to their immediate application, and these secondary costs may be far more significant than the costs of acquisition. Policies focused strictly on acquisition thus may miss much of the mark.

Development is equally difficult to control. Hopes of profits from the high-volume markets encourage private development without major public investment. Also, initial "invention" is often the unintended byproduct of a research effort directed elsewhere. Once "invented," development is difficult to limit in a market where recovery of investment is so certain. Therefore, strategies to limit development directly do not look particularly promising. The success of policies to reduce the cost impact of diagnostic technologies will depend on their ability to limit utilization, and to offset the pressure toward expansion by modifying the current market incentive structure.

Survival technologies

Survival technologies are those directed at maintaining the life of the patient until further medical care is available or can be applied, or until the natural healing capacity of the patient can overcome the threat to life. Such cases are dramatic, and much public policy has been directed at maximizing access to and distribution of survival technologies. The Emergency Medical Services Systems Act aims at broader access by patients suffering from life-threatening accident or illness. It also encourages development of new life-supporting technologies and procedures that can hasten the entry of the victim into the medical care systems. The prevailing view is that the benefits derived from the technologies legitimize their costs.

From other sides, however, the identical technologies draw much criticism and many accusations of waste. There is growing concern at the cost of sustaining the lives of the dying and of supporting life where there is no hope that the patient's condition will ever change through survival technologies. The Quinlan case provided some fuel for this point of view, even in a context where concern with the impact of survival technologies on conventional definitions of mortality was predominant.

These differences illustrate a major dilemma. The widespread availability of survival technology is seen as justified in emergency situations where time and immediate access are critical. Therefore, a policy of encouraging applications has found widespread support. However, once in place, intensive care units and other survival technologies become a part of a medical care system dedicated, even obligated to sustain life. This commitment is quite independent of any expectation that with survival will come improvement or reduced dependence on artificial life support. Indeed, as is the case with diagnostic technologies, failure to utilize a survival technology, where it is available and could be indicated, may be far more costly to the care provider, in terms of exposure to malpractice risk, than using it when no further improvement in the patient's condition can be made. (Excess capacity may make such applications relatively inexpensive initially, but secondary costs and the inability to limit use will inevitably result in increased costs.)

While survival technologies present many of the same characteristics as diagnostic technologies, from a policy standpoint they represent very different problems. For survival technologies, the application always is linked immediately in time to patient mortality. Therefore the technology is seen as necessary, even if not sufficient. This argues against constraints on distribution. In the absence of any criteria to limit application to those cases where survival can be followed up with improvement, survival technologies will continue to be utilized in circumstances where patient mortality is inevitable, and the costs associated with that mortality will be significantly increased.

In the case of survival technologies, malpractice considerations only reinforce the basic tendency of the medical care system. For a policy to run counter to this, it would have to provide a basis for differentiating between "good" survival and "not good" survival—an extremely difficult task. Without clear choice criteria, limiting access to survival technologies will be difficult. The development of such criteria should receive a high priority.

Illness management technologies

This category is directed at offsetting or ameliorating the effects of a specific disease or illness. The development and application of renal dialysis for end-stage renal disease is one such technology; insulin therapy for diabetics is another, as is the developing technology of rehabilitation embodied in vision enhancers, light sensors, and new prosthetics. In most cases, potential applications and, therefore, maximum benefits are limited to current and projected rates of incidence of the condition being managed (if the technology is not essential to survival), or prevalence of the condition (if the technology is essential to survival). This provides an upper limit to the potential volume of use and the distribution of benefits.

With regard to effects, illness management technologies are of two kinds. Some, such as renal dialysis, are associated with survival; others, such as prosthetic devices, are unrelated to survival but affect the degree of disability associated with the illness.

It seems clear that when technologies are essential for survival, limiting development is difficult. The direct and highly visible evidence of such benefits provides development with a driving stimulus and restricts the possibility of limiting application. The medical criteria that support their use are clear. If the benefits also accrue to groups in the political mainstream, pressures for public support may be irresistible.

From the cost side, such technologies have significant implications. By enhancing survival, they increase prevalence over time of the illness, and hence of the technology. If the operating costs of the technology are significant, the resources devoted to that particular form of medical care will continue to rise until limited by the eventual mortality rate of the treated cohorts. The renal dialysis experience is a case in point.

Since limitations on development or application of this type of technology do not have strong support as policy strategies, reducing their cost impact may require *increased* development directed at reducing the operating costs by introducing less expensive technology (i.e., wearable kidneys and alternative dialysis strategies). Alternatively, one can hope that the upper limits of full utilization will be fiscally tolerable.

For illness management technologies not linked to survival, the circumstances are much different. The valuation of benefits is much more speculative, and the costs of nonapplication of the technology may fall outside of the health care system.

When the new technology is incorporated into the functions of providers currently caring for the patients who will derive the expected benefits, those benefits can be small and yet suffice to stimulate wider application. The growth of nuclear medicine and open heart surgery reflects these influences. Reimbursement policies which pay for services within these settings, coupled with the malpractice influences noted earlier, reduce cost impacts and hence the valuation of benefits. The cost of maintaining and operating such technology is incorporated within the overall cost structure of the provider institution and, as capital costs are reduced, little direct ability to limit application is evidenced.

Buried within the increased "intensity of care" which accounts for much of the rise in hospital costs is the adoption of this type of technology. The addition of the capacity to perform new surgical procedures influences the costs of care even if such procedures are not performed, and control of either development or application is particularly difficult for technologies which represent new (more costly) configurations of existing resources rather than new capital expenditures, which can be at least monitored through Certificate-of-Need or similar oversight.

The current interest in expanding clinical effectiveness studies is directed primarily at this type of technology, both to justify new adoptions and to validate currently utilized procedures. In the absence of rigorous clinical evidence of benefit, the mere presumption of possible benefits now serves to stimulate wider application and generate increased costs. Effective limitation requires a means for establishing clinical benefit criteria to justify adoption or provide valid support for rejection of a new technology. Such clinical criteria are essential if cost containment policies directed at reducing available technology are to be viable.

The pressures to expand the development and application of illness management technologies come both from the ease with which current reimbursement policies enable the increased costs to be absorbed and from clinical pressures to make available all services and procedures which *might* have a positive impact, particularly when they do not increase the patient's risk. For many areas of illness management technology, however, the conditions causing these pressures do not prevail. In particular, rehabilitation and daily living enhancement technologies tend to be applied, if at all, outside the mainstream of medical care; there is often no reimbursement, and the "malpractice costs" of not making technology available are not seen as significant. This leads to a curious set of circumstances. If a new illness management technology is encompassed within the medical care delivery system (and covered by medical care reimbursement), then small expected future benefits will be sufficient to generate a high likelihood of adoption and incorporation into the "standard medical care menu." On the other hand, illness management technologies that fall outside the system are likely to be underutilized in relation to their expected benefits. This is particularly true in the areas of long-term care, chronic disease treatment, and rehabilitative services. A technology policy that fails to consider applications outside the medical care delivery system will perpetuate this imbalance in the allocation of resources. Growing evidence on disability levels in the population suggests large potential benefits from encouragement of development of technology in these areas.

Cure technologies

Cure technologies are designed to alleviate or eliminate virtually all of the disasbility associated with a particular illness or disease. Included in this category are procedures, such as heart repairs, hip joint replacements and transplantation, and treatments, such as antibiotic therapy and the recent application of long-term, low-temperature maintenance of a patient in a Washington hospital to offset an otherwise untreatable infection. While the costs of cure technologies can be quite high, they tend to be incurred, unlike those of illness management technologies, over a relatively short time, and their benefits are a function of the value placed on recovery.

The pressures toward applying developed cure technologies are similar to those toward applying survival technologies. The visible and highly valued benefits from cure technologies often are compelling in direct relation to the incidence of the disease addressed, but also in some cases (i.e., children's diseases) to the particular population affected. Furthermore, successful application of cure technology is central to the conventional image of what research and development is about. Limitations on applications are often hard to implement.

Cure technologies have received attention as a cost-increasing activity. In particular, criticism has been directed at devoting resources to procedures such as hip joint replacement for elderly patients where benefits are viewed as being less significant. What is at issue here is not the basic legitimacy of the cure technology but rather the notion that all applications are not of equal benefit, an idea earlier addressed with respect to diagnostic technologies. This aspect of cure technologies has implications for both development and application.

Perhaps more important, cure technologies often require, for their benefits to be generated, a number of complementary developments which also must be incorporated into a policy for managing medical technology. For example, the benefits which can come from successful organ transplantation depend greatly on the state of technology of tissue typing and organ storage, areas of development not supported by the payment system for medical care services. The transplantation procedures themselves readily are incorporated into the current medical care services delivery system, both for purposes of using resources and for receiving payment. However, the success of such procedures and the benefits to be obtained from them are sensitive to activities which require deliberate investment decisions made outside the delivery system. This linking of technology development and application strategies is a central aspect of most cure technologies and is a required element of effective policy in this area.

It is possible to expand the application of some cure technologies, particularly those involving surgical procedures, in ways that reduce the anticipated benefits. Experience with open-heart surgery and transplantation procedures provides strong support for concentrating technologies in settings where the volume of service and quality of management assure maximization of potential benefits. Whereas the reason for limiting availability of some diagnostic technologies was to restrain utilization, for cure technologies the lack of restraint is not the central issue. Rather, the concentration recommended as policy is directed at assuring a scale of operation which can optimize outcomes. (In truth, wider availability generates some increased use, but it will often be reflected in even poorer outcomes.) A policy of limiting application through franchising, reimbursement limitations, or other means also has the potential to reduce system costs by concentrating overhead in fewer settings.

Policies on the development of cure technologies then must reflect the interdependence of technology developments outside the medical care system, and the benefits that can be derived from application of a given technology. Policies on applications must counteract the ease with which the system supports new cure technologies by limiting application to a level at which quality is reflected in patient outcomes, and the potential benefit from the new technology can be realized.

Prevention technologies

Prevention technologies are directed at reducing the incidence of mortality and morbidity in a given population. The development of vaccines is one such technology; diet control for babies with low phenylalanine levels to prevent mental retardation is another. The growing attention being given to inborn errors of metabolism such as Down's Syndrome and phenylketonuria has raised the possibility of genetic screening as a preventive technology. The category also might include using appliances to correct bad bone growth patterns in some babies. While this procedure might be seen as a cure, its function is often to avoid further orthopedic problems, and it can be thus viewed as preventive.

Development and application strategies for prevention technologies present a number of special issues. Potential benefits from such technologies reflect both the prevalance of the disability and its severity. Often, extensive epidemiological research is necessary to identify prevalence and, therefore, the existence of potential benefits. Improvements in test procedures and the development of early pediatric screening increase awareness of prevalence and thus stimulate the development of new preventive technologies.

While preventive technologies may have significant impacts on health care costs, their development and often their applications are not incorporated into the service reimbursement system that pays for the failures of prevention. Development resources come primarily from funds for research, and applications have been financed from public health and welfare resources or individual payments.

A policy designed to manage medical technology (particularly if stimulated by cost considerations) would do well to address the problem of ensuring adequate resource commitments for preventive technologies in a system where many other technologies have ready access to resources for application and often for development.

From the standpoint of both benefits and costs, successful prevention technologies have high payoff, and a modest continuous investment on the part of the medical system would seem easy to justify. An important consideration is the difficulty often encountered in sustaining the application (and therefore the benefits) of such technologies when they are not routinely incorporated into the system. The high percentage of children *not* immunized against polio provides evidence of this problem. The assurance that applications of medical technology will occur at a scale sufficient to generate benefits merits as much attention as avoidance of unproductive applications.

While the above discussion has focused on medical technologies, prevention technology provides a stimulus to look beyond this limit. In one sense, passive passenger restraints in automobiles and smokestack scrubbers can be seen as nonmedical prevention technologies. The growing attention being paid by all industrialized countries to the contribution of industrial processes and personal behavior to morbidity and mortality suggests that this frame of reference is a useful one. From a cost containment perspective, such technologies may be among the most promising. Here too, the assessment of costs and benefits provides a guide to development and application, although implementation of policies falls outside the operation of the medical-care system.

System management technologies

While not strictly medical, there is another class of technologies, called here system management technologies, which has significant implications for costs of medical care. This category includes medical information systems and telemedicine systems. The costs of such technologies are incorporated into the operating structure of the medical care providers, and their benefits are reflected in a capacity to manage increasing amounts of information within or among service-providing settings or to substitute moving information for moving patients or providers.

Stimulated by ease of cost recovery and routine operation, clerical systems for billing and inventory control have been developed commercially and marketed widely. On the other hand, medical information systems have been developed primarily through public research and demonstration efforts. The benefits from these system management technologies are subtle, and their implementation often requires modification of medical practice which may limit their acceptance or, in some cases, may compromise availability of reimbursement for them.

But system management technologies have great potential to impact on the costs of and benefits from medical care generally. Therefore, any typology of medical care technologies to be complete must include them, and any policy based upon such a typology must take them into account.

Summary

This paper is intended to contribute to a productive discussion of the contribution of new medical technologies to health care costs and its implications for policy. To this end, it identifies a number of categories of medical technologies in terms of their objectives (expected benefits). Influences on the development and application of each technology type are explored, as are differences in access to resources when that access is not related to expected benefits or benefit-cost relationships. Of central concern is the degree to which the current deployment of new medical technology reflects reimbursement policies which reduce the limiting influence of costs, and malpractice considerations which overvalue some potential benefits by raising the cost of omission. These characteristics do not influence each type of technology to the same degree, but policies to rationalize the investment in technology and to ameliorate its cost impacts must contain explicit strategies to offset them, or the policies are likely to prove ineffective.

End-stage renal disease and the "cost" of medical technology

Richard A. Rettig

Introduction

End-stage or chronic renal disease is the clinical condition of patients who have experienced such a degree of irreversible deterioration of kidney function that, without treatment, death will soon follow. In the early 1960s, two therapies emerged that were life-extending for victims of this disease state. One was *hemodialysis,* the process by which metabolic waste products—normally cleared by the kidney through the urinary tract—are "washed" from the blood steam by an artificial kidney. The other was *renal transplantation,* a surgical procedure by which a healthy kidney from one individual is implanted in another with end-stage renal disease, and the transplanted kidney functions as the recipient's own kidneys once did.

Both therapies, but especially hemodialysis, were and have remained highly expensive, a fact widely recognized from the outset. They were so expensive, in fact, that payment of treatment costs was well beyond the capabilities of most individuals and families involved. Consequently, this country was confronted with the dilemma of having life-saving medical technology available that was inaccessible to its citizens because of its high cost, a dilemma that was dramatized through both national print and broadcast media.[1,2]

A long policy debate occurred from the mid-1960s until 1972 about the federal government's responsibility for the payment of the costs of patient care.[3] There was a series of partial federal policy and program responses, but no direct provision for patient care financing for the general population was made until the enactment of Public Law 92-603, the Social Security Amendments of 1972: Section 2991 of that law extended Medicare coverage for chronic kidney failure to any individual under 65 years of age who is "medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease," if the person is fully or currently insured or entitled to monthly benefits under the provisions of the Social Security Act, or is the spouse or dependent child of such a person.[4] Such individuals represent more than 90 percent of the United States population.

More than five years have elapsed since Section 2991 went into effect. Some 40,000 patients are currently benefiting from the End-Stage Renal Disease Program authorized by this provision and by the related Medicare provisions (those in the Social Security Amendments of 1972 relating to the disabled, and those for persons over age 65).[5] Yet the nation's experience with this program remains troublesome to many citizens, including scientists, physicians, executive branch officials, and members of Congress.

One of the main purposes of this paper is to probe the sources of distress about this program. Another is to extract from this case the lessons that could be applied to other expensive, life-saving technologies. Before proceeding, however, it is useful to recapitulate briefly the historical development of both hemodialysis and renal transplantation, to acquire perspective on the processes by which new medical technology is generated, and to review the manner by which these therapies were introduced.

Background

The development of medical technology[6]

Hemodialysis. The search for an artificial substitute for the kidney dates from the early part of this century. In November 1912, Abel, Rowntree, and Turner, working at Johns Hopkins, performed an experiment that involved drawing blood from dogs, passing it by an arterial cannula through a tubular "celloidin" semipermeable membrane, and filtering diffusible substances from the blood back into the animal through a venous cannula.[7] These experiments established the conceptual basis for dialysis but encountered two major obstacles: the lack of an effective anticoagulant and the absence of an effective membrane. The first of these problems was solved in 1918 when investigators doing research unrelated to kidney disease developed heparin. The second solution emerged in the 1920s when cellophane was commercially produced for the first time, initially for use as sausage casing.[8]

The first artificial kidney machine was developed in Nazi-occupied Holland in the early 1940s by a Dutch physician, Willem J. Kolff, who developed a rotating drum through which a cellophane sausage casing was wound. The blood from the patient was passed through the casing, which was rotated constantly through a dialysis bath, and passed back into the patient. The first effort to use this new machine was made in 1943. The first 16 patients on whom treatment was attempted died, but the seventeenth patient revived from a uremia-induced coma and lived.

On his first trip to the United States in 1947, Kolff (who later emigrated to the United States) provided the medical researchers at Peter Bent Brigham Hospital in Boston with the engineering drawings of his machine, and the first machine built in this country was known as the Kolff-Brigham machine.[10,11] An interesting sidelight suggests that simultaneous invention was occurring. Kolff published his results in 1944,[12] but soon thereafter Alwall in Sweden and Murray in Canada published similar results of their experience with clinical dialysis.[13,14] The three physicians had been working independently of each other and, until the appearance of Kolff's article, without knowledge of each other.

The Kolff kidney and the Skeggs-Leonard kidney (a different type) were used by a small number of physicians from 1947 to 1960 to treat acute, reversible kidney failure. Patients suffering from acute failure could be restored to health by use of the machine, while those with chronic failure could benefit from it only so long as they were connected. If the machine was disconnected, the patient would soon die.

The major limiting factor for chronic patients was the problem of vascular access. In early 1960, Belding H. Scribner and his colleagues at the University of Washington Medical School in Seattle invented a permanently implanted subcutaneous cannulae-and-shunt apparatus that permitted repeated connections to be made between patient and machine at the same site. They described the technique in this way:

> In the process of trying to simplify the technique of continuous hemodialysis, the problem of long-term cannulation of arteries and veins presented itself. The technique which has been developed and is herein described solves this problem by making use of two devices. First, the cannulas are placed in the vessels through a subcutaneous tunnel so that they emerge from the skin through a tight-fitting puncture wound some distance from the site of vessel cannulation. Second, a special fitting has been developed which permits the arterial cannula to be connected directly to the venous cannula thereby creating a small arterio-venous shunt which will stay open indefinitely during periods when dialysis is not in progress. . . .
>
> This bypass technique has also been applied to the problem of long-term cannulation of patients with chronic renal disease. The technique of insertion is the same except that the tunnels are longer. The long tunnels are used to afford maximum protection against infection.[15]

This critical technological invention ushered in the use of the artificial kidney to maintain the lives of those suffering from chronic kidney failure.

Several aspects of this cannulae-and-shunt apparatus are important for an understanding of the development of new medical technology. First, medical technology is often invented in response to a clinical need perceived by an attending physician. Scribner recounts how he conceived the solution to the problem of the chronic kidney failure:

> We'd had a patient from Spokane who was moribund, and we'd brought him back to life by putting him on an artificial kidney. He responded more dramatically than most, and within three days was walking up and down the hospital corridors. At first, we thought he had reversible renal failure. But when we did a biopsy, we immediately knew it was hopeless. He had acute nephritis, which had destroyed his kidneys. So we had to go through the trauma of telling his wife that despite the amazing recovery she still must take him home to die a second time. It was several weeks after he died, when I was still thinking about the problem, that I literally woke up in the middle of the night with the idea of how we could save these people.[16]

The literature on innovation in general clearly indicates that the great majority of innovations are in response to perceived market needs.[17] [18] The point should not be lost: medical technology often emerges as a physician-inventor's response to a dying patient; this is analogous to demand-induced innovation in other contexts.

The second point about the cannulae-and-shunt apparatus is that the critical material was teflon (the DuPont trademark name for fluorocarbon resins). Teflon was discovered in April 1938 at DuPont's Jackson Laboratory in New Jersey, where scientists engaged in research on "Freon"™ fluorocarbon refrigerants were studying all phases of fluorinated hydrocarbons.[19]

One cylinder of gas, it was noticed, had no pressure, and thus appeared to be empty, yet its weight was the same as when nearly full. Examination of the cylinder revealed a white, waxy solid material inside. The scientists realized that spontaneous polymerization of the gas had occurred, creating a new material. This material did not dissolve in any of the common solvents. These inert properties of teflon, it would later turn out, were critical to Scribner's success; they did not provoke an immunological rejection of the cannulae.

Like cellophane, teflon was developed for completely other purposes than medical applications, yet both proved to be critical to the development of the artificial kidney. As Jewkes, Sawers, and Stillerman have observed, "The discovery of a material with novel physical properties may be tantamount to a reshuffling of all the technical cards in the deck." [20]

Substantial improvements occurred in the early 1960s in the technology of the artificial kidney and the techniques of its use, and a continuing research and development investment was made in this area by the federal government from 1965 onward.

Renal transplantation.[21] The history of renal transplantation also reaches back to the turn of the century. In particular, the method of joining blood vessels by suture, developed by Carrel and announced in 1902, is of critical importance in transplant surgery. The experimental transplanting of kidneys in animals similarly dates to the early part of the century with the work of Ullman in Vienna. He transplanted a kidney from one location in a dog to another, from one dog to another, and from a dog to a goat. Similarly, Carrel performed a number of kidney transplants in animals.

Human transplantation experience dates from 1947, when the first operation was performed by Peter Bent Brigham, and involves three distinct periods. The first, from 1947 through 1953, is transplantation without any attempt to control immunological rejection of the donor organ by the recipient. During this period, Kolff's artificial kidney became available to the people at Brigham, who realized its utility for the preoperative and postoperative care of the transplant recipient. The first human transplant with the aid of dialysis occurred in 1951 in Springfield, Massachusetts. At Brigham, fifteen transplants were performed from 1951 through 1953. All the patients died, usually within a few weeks of the operation and normally from problems later associated with rejection. But the one patient who lived 175 days in early 1953 dramatized the potential of this experimental procedure.

The lessons of this period, enumerated by Moore, were that: (1) a transplanted kidney could restore the chemical and biological balance of the patient with chronic kidney failure, (2) suture connections of blood vessels and the ureter required great care, (3) the abdomen was the preferred location for the transplanted kidney, (4) healthy dogs rejected a transplant more rapidly than humans with chronic uremia, (5) compatibility between unrelated donors and recipients sometimes occurred, and (6) continued high blood pressure of the chronic patient after transplantation indicated the need to remove the diseased kidneys. The histologic processes of rejection were also microscopically described during this period.

Concurrently, an important line of scientific inquiry, spearheaded by Medawar in London, began to develop an understanding of the body's immune response system. The rejection of a kidney transplant by the host came to be understood as the functioning of the immune system. The primary impact of this research would be felt in the early 1960s.

In 1954, however, the developing knowledge of immunology led renal therapy in another direction. Late in that year, at Brigham, a young physician with chronic renal failure received a transplant from his identical twin brother, and the second period of renal transplantation was initiated. The success of the operation meant that homozygotic twins were immunologically compatible and that a solution to the rejection problem existed for this group of individuals. This insight resulted in 49 identical twin transplants and 15 nonidentical twin transplants in the following 15 years. It was learned that a transplanted kidney in the pelvic area could function many years without infection and that the donor twin seldom developed glomerulonephritis, but that the kidney from the uninfected donor was susceptible to further attacks when transplanted into the diseased recipient. This experience also defined the high clinical standard that could be realized through renal transplantation.

During the 1950s, several lines of attack were made upon the immunological barrier (including whole-body irradiation). In 1959 and 1960, Schwartz and Dameshek published results of research showing that certain drugs could increase tolerance for transplanted tissue. Within a few months, new research projects were applying these immunosuppressive drugs to extensive experimental research with animals and to the transplantation of kidneys in humans. Developments from 1961 through 1963 led to the widespread use of immunosuppressive drugs, especially Azathioprine, and ushered in the present period of human renal transplantation. The use of the artificial kidney was greatly expanded by these developments, because transplanters realized that the machine could be used to maintain the lives of potential transplant recipients, as well as to provide preoperative and postoperative care of individual patients.

Subsequent developments in tissue typing and organ acquisition, storage, and transport also have helped kidney transplantation to become widespread.

General observations. From these accounts of hemodialysis and renal transplantation, it is possible to make several observations about the development of medical technology. First, the development processes typically occur over a longer period of time.[20 22 23 24 25 26 27] Second, these processes are frequently international in character, involving individuals and institutions in several countries who are often unknown to one another.[28] Third, while scientific and technical advance in medical technology is sometimes a product of research internal to medicine, it also draws upon general technical developments external to medicine.[29] Fourth, in the case of alternative therapeutic approaches to the same problem, as in the case of end-stage renal disease, the several development processes may interact in important ways. Finally, though no empirical data are presented above on this point, it is easy to understand how a cadre of physicians may begin to collect around a medical technology as it emerges, thus laying the groundwork for its further development and wider utilization.

The introduction to use of new medical technology

It is frequently assumed that the National Institutes of Health (NIH), by virtue of its substantial continuing investment in biomedical research and, to a lesser extent, development, preside over the emergence of every new medical technology. However, this is true only to a limited degree. As this case indicates, medical technology enters clinical practice through multiple institutional pathways.

In fact, the development of hemodialysis as a mode of therapy posed complications for NIH, some specific to the historical period but others persisting to the present. NIH found it difficult to support Scribner's development of the clinical applications of the artificial kidney, and was never prepared to do so on the scale requested by him.[30]

The issue turned on clinical research versus patient care. In the "grey area" between emergent clinical applications and the actual treatment of patients by such applications, NIH came down strongly on the clinical *research* side. Scribner did not invest heavily in research design nor establish strong controls for clinical research. Rather, he pursued a sequential problem-solving approach to keeping patients alive. To NIH and its external review committees, this looked as if they were being asked to fund patient care. Indeed, this was part of the problem. Funds awarded to Scribner for research purposes were used up in caring for patients. NIH felt it had few controls over Scribner in either the purposes for which research awards were used or the rate at which funds were expended.

NIH did support Scribner's research, but with less than enthusiasm. Beyond the idiosyncratic aspects of the situation, at least two general factors were at work. First, the NIH orientation was strongly toward biological and biochemical research, not bioengineering. A conscious search for information about the nature of disease and underlying biological processes motivated NIH, not the quest for "half-way technologies." This orientation, familiar enough to NIH observers of today, was much stronger in the early 1960s.

Second, few mechanisms existed for transmitting research results into medical practice. Not until the mid-1960s did the NIH research contract emerge,[31,32] and Congressional pressure[33,34] led to the establishment of the Artificial Kidney-Chronic Uremia (AK-CU) contract research program in the National Institute of Arthritis and Metabolic Diseases (NIAMD). (Interestingly enough, the AK-CU program was established one year *after* the establishment of the Artificial Heart Program in the National Heart Institute,[35] even though the artificial kidney was more developed at the time. The advocates of the artificial heart were obviously more powerful than those of the artificial kidney.)

The support of research on renal transplantation offered far fewer problems for NIH. The major work in this country was done by individuals with strong research orientation and reputations. The promise of immunology was consistent with an NIH view that genuine medical progress flows from fundamental research, and the costs of patient care were not so ominous when linked, to a surgical procedure rather than to a recurring long-term treatment. Developments in immunology led to the creation in 1964 of a Transplant Immunology Program in the National Institute of Allergy and Infectious Diseases.

Often efforts were made to facilitate the utilization of the artificial kidney. In 1965 the Public Health Service (PHS) established a program that had as much impact on the process as NIH, if not more. The Kidney Disease Control Program (KDCP) funded a number of treatment centers around the country to *demonstrate* the organizational feasibility of dialysis in various settings. Although the contracts that supported these demonstrations were step-funded and eventually phased out, many of these PHS-funded centers became nationally prominent provider institutions, especially in the period before 1973. In addition to Seattle, these centers included Hennepin County General Hospital, the University of Mississippi Medical School, the University of Utah Downstate Medical Center, Charity Hospital of New Orleans, Peter Bent Brigham Hospital, Methodist Hospital of Indianapolis, and St. Francis Hospital in Honolulu. With some notable exceptions, such as Utah, where Kolff was in charge, leadership in these centers often came from young physicians who had made the trek to Seattle to learn how to dialyze patients. These were individuals who frequently saw career opportunities outside of academic medicine and medical research and—very importantly—opportunities to save lives.

When the KDCP became part of the Regional Medical Programs (RMP) in 1969, emphasis shifted from demonstration to building dialysis facility *capacity* in the country.[36] This was done by the dual means of centralized policy and funding control in Washington, aided by an advisory committee composed often of leaders from the PHS-funded centers, and decentralized funding of facilities through the local RMP agencies. The ability of the medical community to absorb the impact of universal financing of treatment by Medicare can be attributed in large measure to the capacity-expanding impact of RMP prior to the 1972 Social Security Amendments.

The kidney experience is also interesting because of the role played by the Veterans' Administration (VA) in its widespread use of dialysis. In 1963, fully two years before the establishment of the AK-CU Program in NIAMD and the KDCP in the PHS, the VA announced its intention to establish dialysis centers for eligible veterans in 30 VA hospitals around the country.[37] It then proceeded to do so over a period of several years. It was, in fact, a 1965 request from the VA to the Bureau of the Budget (BOB) for authorization to use construction funds to refurbish existing facilities for dialysis centers that precipitated the establishment by the BOB of the Gottschalk Committee to review the implications of therapy for end-stage renal disease for the nation as a whole.[38] At the time of passage of the 1972 amendments, VA hospitals were dialyzing one-fourth of the nation's dialysis patients.[39]

Observers frequently overlook the Veterans' Administration's influence on the evolution of health policy in this country, and fail to appreciate how critical a role it can play in the emergence of new medical technology. Not only can it constitute an institutional pathway to the use of a new medical technology, but, equally important, its decision processes involve an entirely different set of bureaucratic and political actors from those involved with HEW.

"Cost" problems of the End-Stage Renal Disease Program

Though enactment of Section 2991 resolved the policy debate about how to pay for end-stage renal disease treatment, the implementation of the End-Stage Renal Disease Program has been hampered by other troublesome problems relating to both dollar and noneconomic costs.

- Throughout the program's early history, there has been a persistent underestimation of total program costs.
- The expectation that the cheapest mode of dialysis therapy—home dialysis—would be widely used has not materialized.
- The promise of increasing success of cadaveric transplantation has not been realized.
- The persistence and deepening of patient quality-of-life problems was not fully anticipated.
- The hope that major advances in therapy would flow from research and development has not been fulfilled.
- The prospect of preventing end-stage renal disease appears to be remote.
- The manner in which Section 2991 was enacted raises questions in retrospect about the adequacy of the policy making process.

Underestimation of program costs

A major problem for the End-Stage Renal Disease Program initially was the difficulty of estimating how much it would cost. Many estimates were made by various individuals and organizations. These estimates were based upon different assumptions and time spans, were never comparable, and had little in common except that they were all too low.

In the 1972 Senate floor debate on Section 2991, Senator Hartke of Indiana, sponsor and floor manager of the provision, said that preliminary estimates indicated an annual cost of approximately $250 million at the end of four years, with the first full-year cost at about $75 million. In the same speech he added, "The $90 to $110 million that this amendment will cost each year is a minor cost to maintain life."[40] Senator Wallace Bennett of Utah, the only person to speak against the amendment, said that the costs of the provision were estimated to be "between $100 million and $250 million," but did not state the assumptions on which these figures were based.

When the House and Senate conference committee on H.R. 1 met in mid-October, the Social Security Administration provided it with actuarial cost estimates for the kidney disease provision, according to whether an eligible patient would be required to wait three or six months for benefits (Table 1).[41] The Senate amendment stipulated six months, while the House favored the shorter period.

After the renal disease program was enacted, Ronald M. Klar, M.D., Office of the Assistant Secretary for Health, HEW, became disturbed by the cost estimates for it. After extensive conversations with nephrologists and transplant surgeons around the country Klar developed five-year projections of his own (Table 2).

"It is critical to recognize," Klar wrote, "that a new cohort of patients becomes eligible each year, while many patients in preceding cohorts would still be alive and require continued threatment." Pointing out that his figures were national figures, not government expenditures only, he stated that the government spending would be less than 20 percent lower. He also predicted that by the time the program reached a "steady state" in its tenth year the annual cost would average nearly $1 billion.

HEW made these data available to Richard Lyons of *The New York Times*, who used them in a dramatic, though inaccurate, front-page story on January 11, 1973.[42] This was followed up by an editorial on Sunday, January 14, in which *The Times* lectured the Congress on the inaccuracy of its earlier figures as another example of "Congressional fumbling with health matters."[43] In response, the National Kidney Foundation said that there would be 13,000 new beneficiaries, not 5,000 as alleged by Lyons, but refused to project beyond the Social Security Administration cost estimates.[44] This episode raised serious questions about the bases of Congressional action, though it did little to clarify the estimates problem. However, by the time the program became effective, on July 1, 1973, HEW was projecting first year costs of $250 million.

The clearest public indication of the underestimation of costs was provided in 1975 by two successive documents of the House Ways and Means Committee. A committee print, dated June 24, 1975, presented the costs actually incurred by Medicare in fiscal year 1974 for all renal disease beneficiaries including the aged, the disabled, and the Section 2991 patients.[5] The total for the three benefit categories, $250 million, was higher than the

Table 1
Estimated expenditures for the Kidney Amendment (Section 2991)
($ million)

	Waiting period for beneficiary entitlement	
Fiscal year	*6 months*	*3 months*
1974	$102	$135
1975	158	176
1976	198	223
1977	252	278

Source: Office of the Actuary, Social Security Administration, n.d.

Table 2

HEW/OASH projections of total national costs, End-Stage Renal Disease Program[a]
($ millions)

Fiscal year	Projected costs	Estimated patient population
1974	$157.7	9,980
1975	281.5	18,754
1976	394.5	26,746
1977	497.8	34,036
1978	592.1	40,685

Source: Department of Health, Education, and Welfare, Office of the Assistant Secretary of Health, 1972.

[a] Assumes: 10,000 new patients a year, 2,000 of whom will be transplanted; first-year transplant failure rate of 40 percent; average annual cost of dialysis of $16,000.

amount ($157.7 million) that Klar had projected earlier for the whole nation (Table 2). The committee print tersely stated that "the costs for renal patients will exceed $1 billion by 1984."

In October 1975, the House Ways and Means Committee issued a report which compared, for fiscal years 1976 and 1977, the estimates used by the Congressional conferees in 1972 and the revised estimates the Committee had published in June.[45] The updated estimate of fourth year costs for Sec. 2991 benefits exceeded the estimates used by the Congress for the fourth year by $108 and $82 million, respectively, for the 6-month and 3-month waiting periods. The updated estimate of fourth year costs for all renal benefits (aged, disabled, 2291) more than doubled the highest estimate used by Congress in 1972. The Committee report indicated that the administration . . .

> now reports that the cost of the program will be $1 billion by 1984 for the treatment of some 50,000–60,000 patients. Health providers see higher costs, possibly as much as $1.7 billion per year (in 1975 dollars) by 1990 for the treatment of 50,000–70,000 patients.[45]

At a hearing of the House Ways and Means Committee's Subcommittee on Health on April 25, 1977, the latest SSA Office of the Actuary estimates of total Medicare renal costs were dramatically announced:[46] in 1982, the costs were estimated to be $1.9 billion, trebling by 1992 (Table 4).

Finally, a summary of actual and estimated total Medicare costs from fiscal years 1974 through 1983, again prepared by the SSA Actuary's Office, was published in 1977 by the National Institutes of Health (Table 5).[47]

The estimates presented in Tables 1–5 are not truly comparable because they were based upon differing assumptions about total patient population, proportion of patients transplanted, proportion of home dialysis, length of entitlement waiting period, and average cost of treatment. However, in Table 6 an attempt has been made to consolidate several of the estimates and the actual cost data for fiscal years 1974 through 1977. The data indicate that:

- The estimates for Section 2991 used by the Senate in its deliberations were inaccurate for the first year, got worse in successive years, and failed to consider total Medicare or total national costs.

Table 3[5]

Medicare renal disease benefits fiscal years 1974 and 1975, incurred costs ($ millions)

Fiscal year	*Sec. 2991 patients*	*All renal patients*
1974[a]	$150	$250
1975[b]	225	350
1976[b]	300	500
1977[b]	360	600

Source: House Ways and Means Committee, June 1975, using data from SSA Office of the Actuary.

[a] Actual.

[b] Estimated.

Table 4[46]

Spring 1977 estimates of Medicare costs for end-stage renal disease benefits[a] ($ billions)

Fiscal year	*Estimated costs all Medicare*
1982	$1.9
1987	3.6
1992	6.3

Source: House Ways and Means Committee, April 1977, using data from SSA Office of the Actuary.

[a] Assuming that: the annual rate of increase for new entrants into the patient population will be 4 percent starting in fiscal 1978, declining to 0.5 percent per year in 10 years; mortality will be 25 percent per year for transplant patients and 19 percent per year for dialysis patients; 28 percent of patients will be transplanted and 72 percent dialyzed; dialysis patient distribution will be 25 percent in home, 70 percent outpatient, 5 percent inpatient; dialysis is required 3 times a week and self-dialysis training requires one month (basically 13 sessions); dialysis costs will range from $75 to $250 per session depending on mode of treatment; transplant costs will average $25,000 per operation; and inflation rates will be 14 percent per year for hospital costs, 10 percent per year for nonhospital costs.

Table 5[47]

Actual and projected costs for end-stage renal disease, 1974–1983 ($ millions)

Fiscal year	*Total costs to Medicare*	*Total national costs*	*Patient population*
1974[a]	$ 242.5	$ 286.2	18,848
1975[a]	404.6	479.5	25,654
1976[a]	573.3	684.2	31,631
1977[b]	757.1	901.9	37,106
1978[b]	958.5	1,143.3	41,939
1979[b]	1,176.4	1,404.4	46,121
1980[b]	1,421.1	1,695.6	49,802
1981[b]	1,667.7	1,992.7	53,077
1982[b]	1,941.7	2,321.6	55,911
1983[b]	2,235.1	2,674.3	58,391

Source: National Institutes of Health, 1977, using data from SSA Office of the Actuary.

[a] Actual.

[b] Estimated.

Table 6
Consolidation of estimated and actual cost data, End-Stage Renal Disease Program, fiscal years 1974-1977
($ millions)

Fiscal year	Source of estimate	Sec. 2991	Total Medicare	Total national	Patient population
1974	Senate, '72	$102			
	Conf., '72	135			
	HEW, '72			$157.7	9,980
	W&M, '75	150	$250		
	Actual		242.5	286.2	18,848
1975	Senate, '72	158			
	Conf., '72	176			
	HEW, '72			281.5	18,754
	W&M, '75	225	350		
	Actual		404.6	479.5	25,654
1976	Senate, '72	198			
	Conf., '72	223			
	HEW, '72			394.5	26,746
	W&M, '75	300	500		
	Actual		573.3	684.2	31,631
1977	Senate, '72	252			
	Conf., '72	278			
	HEW, '72			497.8	34,036
	W&M, '75	360	600		
	Actual[a]		757.1	901.9	37,106

[a]Estimated 1977 (see Table 5)

- The Conference Committee estimates for Section 2991, based upon the three-month waiting period, were reasonably close in the first year, got worse in successive years, and failed to consider total Medicare and total national costs.
- The HEW patient population estimates were low for the first year but improved with successive years; the cost estimates were biased downward as a result of the patient population estimate and the absence of an adjustment for inflation.

Wherever the truth lies about the future costs of maintaining the population of end-stage renal disease patients on dialysis and transplantation, two things are clear: the cost will be substantial, and it will be substantially greater than the initial estimates.

The clinical experience

Clinical experience with home dialysis, cadaveric transplantation, and patient quality of life has been a source of distress to the End-Stage Renal Disease Program. Unfolding realities have not matched expectations and have had an important effect on costs.

Home dialysis. In the 1972 Senate floor debte on Section 2991, it was pointed out on two occasions that the cost of home dialysis was substantially lower than center dialysis treatment.[40] A statement by the National Kidney Foundation, "Facts and Fiction About the Artificial Kidney Machine," inserted in the *Congressional Record*, indicated that "about half of the patients on the artificial kidney are being treated in their own homes. . . ."[40] A *New York Times* story also inserted in the *Congressional Record* contained three brief paragraphs on the preference of "many kidney experts" for home dialysis for financial reasons.[40] Senate discussion on the point was, however, perfunctory.

Since 1973, the proportion of patients being treated by home dialysis has steadily declined. On July 1, 1972, a few months before enactment of Section 2991, the *National Dialysis Registry* had reported that of 5,659 patients alive on hemodialysis, 2,291 (or 40 percent) were being treated at home. The Registry also reported that home dialysis was increasing: in the period October 1969 through October 1971, its annual growth rate had been 46.2 percent, as opposed to 32.7 percent for dialysis at centers. But the data reported by the Registry for October 1, 1973, three months after the effective initiation of the program, indicated that of 9,640 patients alive on hemodialysis on October 1, 1973, only 33 percent (3,171) were on home dialysis.[48] That was down from 37 percent on January 1, 1973. By July 1975, the percentage of home dialysis patients was 25; as of calendar year 1976, less than 10 percent of new dialysis patients were initiating home dialysis.[49]

The cost implications of this trend are substantial. A General Accounting Office study, based on 1972 data, reported center dialysis charges ranging from $11,500 per year to $49,100, with an average over 96 facilities of $30,100.[50] Average home dialysis charges for ten programs were reported to be $14,900 for the first year, in which equipment is purchased and training occurs, and $7,000 for succeeding years. Similar data were developed by a recent NIH study of dialysis treatment costs in five facilities.[51] This study generated annualized costs of $6,729 for home dialysis, $16,520 for limited care dialysis, and $24,738 for in-hospital dialysis. The treatment costs for home dialysis *training* were higher than for all other dialysis treatment modes but were annualized. The data indicate that home dialysis is clearly the least-cost mode of therapy after the first year. A decline in home dialysis therefore has a significant effect on Medicare and total national costs.

That decline is attributable to several factors. [52] Before Section 2991 was enacted, the relative scarcity of resources to help patients pay for treatments created an economic incentive to use home dialysis. That incentive was removed by the 1972 legislation. Patients who are not forced to use home dialysis may wish to avoid the accompanying phychological stress upon themselves and their immediate families. Under Medicare, moreover, an increasing proportion of the dialysis population consists of patients who are aging or who have major medical complications and thus require management in a center or hospital. In addition, though many nephrologists would agree that home dialysis is desirable for those patients who can perform it satisfactorily, no consensus exists among physicians on the percentage of patients who are able to do it.

The most obvious factor in the decline of home dialysis, however, is the fact that Medicare law and regulation introduce financial *disincentives* to its use.[49,52] There are incentives to facilities to provide therapy in an outpatient, nonhospital center, but none to manage patients in the home setting. Similarly, the method of reimbursing physicians encourages them to treat patients in a center rather than at home, and the patients themselves discover that some of the expenses for which they are not reimbursed at home are covered for patients dialyzed in the center or hospital.

Members of the House Ways and Means Committee, especially the Health and Oversight Subcommittees, have been concerned with the proportionate decrease in home dialysis. Representatives Rotenkowski and Vanik introduced legislation in the spring of 1977 that would have required a fixed percentage of all dialysis patients to be treated at home. The percentage proposed was 40 percent by October 1, 1978, then 50 percent by October 1, 1980, with the Secretary of HEW empowered to increase the percentage further at a later time as he deemed necessary.[46]

At an April 25, 1977, hearing on this bill, these statutory quotas were opposed by HEW and by practically all other witnesses, including some of the foremost advocates of home dialysis. In the Health Subcommittee mark-up, the original legislation was substantially modified and H.R. 8423, a clean bill, was reported out.[49] This legislation, subsequently passed by the full House of Representatives, eliminated the statutory quotas for home dialysis patients but declared it to be national policy that a majority of patients be self-dialyzed or transplanted. It also altered the existing incentive structure for home dialysis by:

- Waiving the three-month entitlement waiting period for patients who enter a self-dialysis training program during that time.
- Covering 100 percent, rather than 80 percent, of the cost of supplies in the home setting, including disposables.
- Covering supportive services furnished by facilities to individuals dialyzing at home.
- Covering a self-care dialysis unit maintained by a dialysis facility.
- Authorizing full reimbursement to facilities for purchase of home dialysis equipment used exclusively by home patients.
- Authorizing incentive reimbursement to facilities supervising patients being dialyzed at home.

The bill also removed disincentives to renal transplantation by waiving the current three-month waiting period, extending the period of coverage from 12 to 36 months after transplantation, providing for immediate resumption of coverage if a transplant fails and the patient must return to dialysis, and covering the expenses of live kidney donors. The bill was passed by the House on September 12, 1977.

The Senate, after a controversial hearing in October, reported out a bill that was passed on April 10. The Senate eliminated the language declaring it "national policy" that a majority of patients be on self-dialysis or transplanted. (It also struck some House provisions dealing with "network" organization of the ESRD delivery system.) Otherwise, the Senate bill left intact the changes in the incentives for home dialysis.[53]

Complicated negotiations between House and Senate, designed to avoid a joint conference committee, resulted in a bill passed by both and signed by the President, June 13, 1978. The new law declared: "It is the intent of Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated."[54] The weaker Senate language, rejecting any suggestion of goals or quotas, prevailed. The Senate also prevailed by restoring the 20 percent copayment requirement for home dialysis supplies, a requirement the House would have eliminated. The effects of the new statute on the proportion of patients being dialyzed at home remain to be determined. The new statutory provisions are unlikely to discourage home dialysis, but they may have limited positive effect.

Cadaveric transplantation. Senator Hartke, in the 1972 floor debate on Section 2991, said:

> Perhaps more exciting is the remarkable success that transplant surgeons are having with kidney transplants. It is estimated that over 2,000 transplant procedures will be performed this year in the United States. Of these, 85 percent will be considered successful. It is also important to point out that the 15 percent rejection rate means kidney mortality and not human mortality. These people are placed back on the artificial kidney machine to await another tissue-typing for another transplant. At the present time, the average costs of a transplant are $15,000. Again, we can look at the substantial reductions in the cost of transplantation. Dr. Sam Kountz, a transplant surgeon at the University of California, has reduced his costs to $8,000 per transplant, or no more than any major surgical procedure.[55]

No one in the debate challenged Hartke's figures. In 1972, a "U.S. Kidney Transplant Fact Book," based upon data from the Human Renal Transplant Registry, distinguished between transplants where the organ source was a living relative (excluding monozygotic twin) and those using a kidney from a cadaver. The data for first-year patient and graft (kidney) survival are shown in Table 7. They show that Senator Hartke's 85 percent patient survival rate pertained only to persons receiving a kidney from a living relative. Patient survival for cadaveric transplants ranged from 53.5 percent to 69.1 percent, but those patients with a functioning kidney at the end of one year ranged from a low of 39.3 to a high of 53 percent, with 46 percent being the most recent figure reported. These data hardly support the claim of "remarkable success" made by Hartke in the debate.

In fact, since the advent of Section 2991, the situation with respect to cadaveric transplants has worsened rather than improved. Terasaki and his U.C.L.A. colleagues, in an analysis of yearly transplant survival rates based upon data gathered by them directly from more than 100 North American transplant centers, reported:

> It now appears certain that there is a definite decline in the transplant survival (graft survival) rates with each succeeding year. This trend was reported by us for the first time in 1973 and has continued since. The decrease in the graft survival

Table 7[55]

First year patient survival and transplant function related to living and cadaver donors—first transplant only

	Related living donor			Cadaver donor		
Year of transplant	Sample size	Percent of patients living	Percent with functioning transplant	Sample size	Percent of patients living	Percent with functioning transplant
1967 . . .	202	83.8	78.2	143	53.5	39.3
1968 . . .	265	85.2	76.5	265	53.1	41.2
1969 . . .	314	82.0	74.7	343	65.0	53.0
1970 . . .	360	87.2	77.7	434	69.0	52.3
1971 . . .	187	81.2	64.4	223	69.1	45.5

Source: U.S. Kidney Transplant Fact Book, 1972.

rate is progressive, rather than fluctuating from year to year, and there is a long list of factors that might account for it.[56]

Among such possible factors Terasaki lists declining interest in and research support for renal transplantation studies, an increasing number of newer, inexperienced transplantation centers, an increasing proportion of transplantation of high-risk patients, and increasing reliance upon early graft removal when rejection begins. On the other hand, he finds that newer centers often produce good results and that established centers have experienced a drop in survival rates. He also lists factors that suggest that survival rates should improve: the increasing level of experience within the transplant community, improved understanding of immunosuppressive regimens, and improved tissue typing. Terasaki postulates that "the decrease in the number of pretreatment blood transfusions that has occurred over time may be deleterious,"[56] an explanation that has not been wholly persuasive to the medical community. So the cause of declining graft survival rates remain unexplained, though the facts are not in dispute.

Terasaki's data on *patient* survival rates at the end of one year of cadaveric transplants, first graft only, indicate stability at the 75 percent level from 1969 through 1974. One-year, first *graft* survival rates for cadaveric transplants have declined steadily by approximately 2 percent per year since 1969 from slightly over 50 percent. Thus, a person receiving a cadaveric transplant had a 75 percent probability of being alive one year later but less than a 50 percent chance of being alive with that kidney functioning. Patient survival rates at the end of one year for transplants from identical sibling and parent donors have remained at about the 85 percent level, though one-year first graft survival rates have declined steadily for these transplants as well.

Cadaveric transplants grow relatively more important with each passing year. Demographic trends toward smaller families and fewer siblings reduce the prospective donor pool for living related transplants, and both Terasaki and the Registry indicate a steady decline since 1967 in the ratio of those transplants to the total number.[57] But for cadaveric transplants, steady one-year patient survival rates and decreasing one-year graft survival rates mean that for more and more patients the transplant is merely an expensive surgical procedure temporarily interrupting dialysis. This pattern hardly fulfills the vision of reducing the cost of hemodialysis by increasing the proportion of successful kidney transplants in the total end-stage renal disease patient population.

The present clinical picture then is not encouraging. However, immunological research at the fundamental science level is proceeding at a rapid pace, and if the research results are translated into improved control of immunological rejection, the present trends may be reversed.

Patient quality of life. In the 1972 Senate debate, Senator Hartke said, "Sixty percent of those on dialysis can return to work but require retraining and most of the remaining 40 percent need no retraining whatsoever. These are people who can be active and productive, but only if they have the life-saving treatment they need so badly."[40]

Unfortunately, there is no way to tell whether this optimistic statement is accurate; there is no substantial body of data on which to base any judgment. We have only physicians' statements, some behavioral science literature,[58] some case literature,[59] and numerous anecdotes. The Section 2991 End-Stage Renal Disease Program medical information system, which replaced both the National Dialysis Registry and the Human Renal Transplant Registry, is not yet fully operational. But it is not expected that the system will tell us much about patient rehabilitation.

Rehabilitation of the dialysis or transplant patient is currently beyond the reach of government policy. In the implementing regulations of the End-Stage Renal Disease Program there is a requirement that there be a written patient care plan that "reflects the psychological, social, and functional needs of the (individual) patient," and a further requirement that social services be provided by a qualified social worker responsible "for conducting psychosocial evaluations, participating in team review of patient's progress and recommending changes in treatment based on the patient's current psychosocial needs."[60] However, these requirements do not insure a commitment by a provider facility to patient rehabilitation. Nor are efforts to rehabilitate patients reimbursable under Medicare. The now disestablished Social Rehabilitation Service had statutory authority for rehabilitation activity directed to the end-stage renal disease patients but had no funds for such activity, nor did it demonstrate any keen desire to become involved in this area.

Rehabilitation of patients, in this analyst's view, is contingent upon the commitment of the physician in charge of a given treatment facility. There are several centers around the country—the Northwest Kidney Center in Seattle, the statewide efforts in Minnesota, the statewide program in Mississippi based on the University of Mississippi Medical School, and others—where one finds strong, well developed programs to rehabilitate patients to productive lives. On the other hand, one finds many places where such a commitment is absent. When at Ohio State University, the writer had a dialysis patient speak to a seminar. The individual—white, nearly 40 years of age; a family man, and a member of the city council in a Columbus suburb—had returned to his white collar, professional job after initial dialysis stabilization. But, he was the only patient among approximately 40 being treated in a local dialysis facility who had done so. His action had a powerful effect on the perceptions of the other patients: they had not conceived previously that return to work was possible.

It should be noted that a shift toward center dialysis and away from home dialysis powerfully reduces the probability of patients' returning to work. The reason is simple. Center dialysis patients are dialyzed mainly during the daytime. Treatment for three to six hours, three times a week during the daytime frequently hinders a return to work;[61] home dialysis permits nighttime treatment.[59] In Minnesota, the policy for the treatment of end-stage renal disease was developed essentially by state officials in conjunction with the medical community, and thus reflected the state's emphasis on rehabilitation. It required that facilities to be eligible for reimbursement of patient treatment must provide opportunity for dialysis in the evenings.[62]

The problems of dialysis patients are not limited to the treatments. Patients must adhere to limits on food and fluid intake and are restricted in personal travel. Reversal of dependence relations between spouses can occur. Severe swings of psychic mood are frequently experienced.[58] Loss of sexual function often accompanies therapy.[63 64 65] Medical complications arise because of the limits of dialysis therapy:[66] whereas the normal kidneys perform excretory, regulatory, and metabolic/endocrine functions, the artificial kidney can effect only the excretory and some of the regulatory functions. Consequently, anemia, renal osteodystrophy (bone disease), and other medical problems occur that damage the patient's quality of life.

Patients who have undergone successful transplants are freed of most of these problems, and there is no question but that a successful transplant is the preferable approach. But all transplant patients, save identical twins, require immunosuppressive drugs for the rest of their lives in order to prevent rejection of the donor kidney. This medication makes them vulnerable to infection by reducing their immunological capability. Not surprisingly, infection remains the primary cause of death of transplant patients.[67] Also, the use of steroids to prevent kidney rejection can result in startlingly disfiguring effects.

Another problem exists that is an outgrowth of government policy. The decision to fund end-stage renal disease therapy removed financial constraints as a major patient selection criterion, and as a result the criteria for patient selection have steadily expanded. Formerly, selection among terminally ill patients was restricted to the "best of the worst," but patients who are increasingly marginal (in clinical terms) now are being accepted for treatment.[66] Advanced age, insulin-dependent diabetes, and other clinical complications no longer preclude acceptance for treatment. This means that over time the proportion of marginal patients—who require substantially greater hospitalization for complications than more normal patients—is increasing relative to the total patient population. In the aggregate, rehabilitation prospects are accordingly diminished and the quality-of-life problems increased.

It would be helpful as an aid to informed public policy to have decent data on the quality of life of dialysis and transplant patients. The medical information system for the End-Stage Renal Disease Program will generate only minimal data to that end, and studies that selectively sample the patient population are clearly warranted. In the absence of such data, we should be mindful that the sanguine sentiments of 1972 simply have not been borne out, nor are they likely to be.

The yet unfulfilled promise of research

Prevention of end-stage renal disease does not appear to be imminent, and there is little reason to be hopeful that in the near future the results of medical research will have a substantial cost-saving impact on the nation's expenditures for end-stage renal disease treatment.

A conference on "Prevention of Kidney and Urinary Tract Diseases" was held in May 1976 at the National Institutes of Health;[68] presentations dealt with genetic disorders of the kidney, glomerular diseases, the relation of hypertension to renal disease, renal disease and pregnancy, and acute renal failure. There were some indications of progress over the past decade. One participant said, "Where we once spoke about the 'uremic syndrome,' we are now asking more detailed questions that point to important research questions." Another participant, however, pointed out that each new stage of understanding underscored the realization that the uremic syndrome is not a single disease entity but several, and that each entity in turn may have its own etiology and pathogenesis. Increased scientific understanding of the disease problem, in short, has expanded the research agenda. No one familiar with the state of scientific knowledge believes that prevention of end-stage renal disease is close at hand.

As for therapies, improved technology of the artificial kidney has been the objective of the Artificial Kidney-Chronic Uremia (AK-CU) program of the National Institute of Arthritis and Metabolic Diseases since 1965. This program has indeed generated research results that have improved hemodialysis, mainly in reducing the average length of dialysis time from 6 to 8 hours, to 3 to 6 hours. These reduced treatment times may have enabled institutional centers to live within the "screen" of $150 per dialysis set by HEW in 1973, and may thus be reducing cost to the centers. However, they have not led to reductions in government expenditures for the program. Moreover, since normal kidneys function on a full-time basis, it is likely that reductions in dialysis time are near their natural limit.

Further improvement of artificial kidney technology is limited by our ignorance of the mechanisms of the disease and the mechanisms of therapy. There is little reason to anticipate important technological change in the near future that will have a significant cost impact on Medicare expenditures for end-stage renal disease.

The technique of peritoneal dialysis has emerged from clinical testing and is moving into general use, aided by research support from the AK-CU

Program. A new technique of peritoneal dialysis offers some promise of cost reduction, but it is only in the early stages of clinical testing and the promise is thus to be treated with caution.

The situation in transplantation may be the most promising. Bernard Amos, one of the country's leading immunologists, put the matter this way several years ago:

> Since the Gottschald Report [of 1967] there has been very little obvious clinical progress [in renal transplantation] which is apparent to an outsider. There has been a fantastic accumulation of scientific knowledge, and there is a fair chance of this knowledge being applied within a finite period of time.[69]

The knowledge base in immunology, in short, is being developed at a rapid rate.[70] When this new knowledge will have significant impact upon the clinical situation remains unpredictable.

The above paragraphs should not be construed as opposing either a fundamental or an applied research effort related to end-stage kidney disease. Quite to the contrary, a continuing research investment in the etiology, pathogenesis, and teatment of kidney disease is essential if we are to move beyond today's half-way technologies. But one should be realistic about the lengthy time and substantial difficulties that are typically involved before research results begin to pay off in terms of cost reduction.

The enactment of Section 2991 of Public Law 92-603

The policy debate of fully ten years that preceded the enactment of Section 2991 was resolved by the inclusion of that provision in the Social Security Amendments of 1972. This occurred in the following manner:[3]

The amendment was first proposed on Saturday morning, September 30, 1972, when the Senate, with just over half of its members present, was rushing to complete floor consideration of the numerous provisions of H.R. 1—a very complex piece of legislation, in order to place a bill on the President's desk before the November election.

No hearings had been held on an end-stage renal disease provision for H.R. 1 by either the Senate Finance Committee or the House Ways and Means Committee. (However, it should be noted that the year before, during Social Security Amendment hearings, the House Committee had heard testimony on end-stage renal disease; the testimony had included a demonstration of a patient dialyzing himself.[71])

No more than 20 to 30 minutes of floor time was allocated to the consideration of this far-reaching provision before it was adopted by the Senate.

The joint House-Senate Conference Committee deliberated no more than ten minutes, in a Saturday evening session (October 14), before agreeing to include this provision, slightly modified, in the final bill.

Clearly, the decision-making process that led to the enactment of Section 2991 involved a short circuit of the normal procedure of hearings on proposed legislation. Thoroughness, openness, and deliberate weighing of the issues were not in evidence. In addition, the decision to enact Section

2991 was based upon what we now know to have been underestimated costs and overoptimistic expectations concerning clinical treatment.

Would greater adherence to normal legislative procedures have generated better information for the Congress? Clearly, yes. In that case, would better information have produced a different outcome? If, as one interpretation holds, the Congress did not fully understand what it was doing, then a different outcome might have resulted. Representative Paul Rogers (D., Fla.), chairman of the House Subcommittee on Public Health and Environment, remarked in January 1973, "We in Congress had no idea that costs would be anywhere near that large," upon learning of the estimated costs of the End-Stage Renal Disease Program.[42] Senator Quentin N. Burdick (D., N.D.) was also quoted at the same time as saying that he never would have cosponsored the amendment had he known the true costs.[42] So one possibility is that better information would have led to a rejection of the amendment.

Another interpretation, however, is that Congress may not have known in detail but certainly knew in the main what it was doing. Elsewhere I have suggested that a cumulative process was at work, by which a series of incremental policy changes leads inexorably to a threshold-crossing, major policy change.[3] Payment for patient treatment costs, in this light, was a logical extension of prior government programs in research, demonstration, capacity building, and treatment of veterans. This interpretation is reinforced by the fact that the spokesmen for Section 2991 on the Senate floor—Hartke, Jackson, Magnuson, Dole—had detailed knowledge of prior government policies and programs dealing with end-stage renal disease. Better information, then, might *not* have changed the outcome.

A third question is whether better information would have led to a "better" outcome. In substantive terms, the answer to this turns on one's view of whether the Congress made the right choice. In procedural terms, arguments can be made in either direction. It can be argued, for instance, that the decision of the Congress would now have greater legitimacy with the body politic if it had been more thorough, open, and deliberate in nature. On the other hand, it can be argued that the issue of allocating scarce medical resources for the saving of lives is so profound and potentially divisive that Congress—a conflict-resolving and not conflict-deepening institution—could not have handled the matter any differently. To raise detailed questions in the legislative process about the value of life is not easy, in either political or other terms. Better to keep the issue from arising at all than to raise it and vote no.

A final question about decision making is, what are the implications of this case for similar situations in the future? If scarce resources are to be allocated by the Congress for life-saving therapies of reasonable effectiveness but of high cost, how should such issues be responsibly approached? The absence of a clear answer should be recognized as a challenge to thoughtful people.

Conclusions and recommendations

A number of lessons are suggested from the experience of the end-stage renal disease program. Chief among these are the following:

1. The processes of development of new medical technology are lengthy, are typically international, and draw broadly from the wide frontier of technical advance. There is thus no one logical place to intervene in the development process.

2. The institutional pathways by which new medical technologies flow into actual use are numerous and diverse. There is thus no centralized institution responsible for the introduction of technology to use.

3. The policy decision to provide payment for treatment costs is one of the most important points for the control of medical costs by the federal government. The choice is a simple "go" or "no go," and the latter alternative can be an effective means of cost control. But, the policy decision is normally framed broadly in terms of benefits and costs of saving lives, with the former typically overstated and the latter understated, and cost control is generally a later and subordinate concern. The likelihood that cost control considerations will enter into the initial policy decision is not high.

4. Initial cost estimates will tend to understate actual costs. Such estimates are difficult to make under the best circumstances, and they are often developed under numerous constraints: inadequate data, inappropriate assumptions, limited understanding of the probable dynamics of a complex program, shortness of time, and a context where the advocates of action have a vested interest in downplaying cost estimates. Thus, improvement of initial estimates is both technically and politically a difficult task.

5. If politically feasible, however, cost control measures should be incorporated into the design of the reimbursement system at the inception of a patient treatment program. An effort to do this should be made even if not feasible; a deliberate initial signal of concern may facilitate subsequent action. Efforts to build cost control measures into an on-going operational program will affect existing distributions of institutional and personal self-interest. They will thus appear to be, or be characterized as appearing, arbitrary and draconian, and thus will generate substantial opposition.

6. The political resources of the bureaucracy will seldom be adequate to introduce cost control measures that alter existing patterns of interest. Thus, the Congress must be looked to as the institution for trading off cost control measures against other legitimate objectives.

7. Initial efforts to predict the dynamics of clinical developments, even if made, are likely to be wrong in important respects. Provision should be made at the outset for relatively modest studies, based upon a sampling strategy, to be done annually with respect to unfolding clinical patterns, associated cost implications, and feasible cost control responses. Similar studies should be done with regard to patient quality-of-life issues.

8. Continuing research and development are needed with respect to etiology, pathogenesis, treatment, and prevention of disease states for

which there is a major patient treatment benefit program. Dialogue between federal reimbursement agencies and federal research agencies should be encouraged to insure widespread consensus about the appropriate level and distribution of research effort. Even so, it should be kept in mind that the practical application of research results requires a lengthy period of time, and caution should be exercised with respect to overoptimism about research.

9. Policy decisions that involve the allocation of scarce medical resources for the saving or prolonging of relatively few lives deserve thoughtful deliberation at the time they are made. Ideally, the Congress is where such deliberation should occur when the allocation of federal government resources is involved. If such issues are too difficult for thorough, deliberate consideration by a legislative body, however, alternative institutional mechanisms for considering the manifold implications of these difficult allocative issues should be considered.

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The computed tomography (CT) scanner*

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Introduction

The computed tomography (CT) scanner provides an instructive case study of governmental policies regarding the development, diffusion, and use of medical technologies. Some of the federal policies are new, and the CT scanner was the first major piece of equipment to test their functioning. Evaluation of these policies does not entail passing judgment on the rate at which CT scanners were adopted or their value for patient care. Such a review does reveal certain shortcomings that apply not only to CT scanners, but to medical technologies in general.**

Although CT scanning had been more carefully studied than many other technologies, its widespread acceptance still preceded a complete and systematic assessment of its efficacy. Evaluating the efficacy of diagnostic technologies such as CT scanning does pose special problems; nevertheless, no public or private body has responsibility for these evaluations, including such aspects as conducting studies and collecting and analyzing data. The resultant lack of information has hampered a variety of federal programs and policies, including those related to medical devices regulation, utilization review, health planning, and reimbursement. Furthermore, reimbursement methods prevailing in the private and public sectors encourage the provision of additional services and do not stimulate a choice among alternatives or an evaluation of their relative costs and benefits.

Development

CT scanning is a diagnostic radiological procedure used mainly for imaging the head, but also the body. A CT scanner makes use of conventional X-ray, but collects and processes information in a new way. A source emits X-rays from several positions, and a detector collects and measures the energy remaining after the X-rays have passed through the portion of the body being scanned. A computer, after processing all the data, constructs and displays on a screen an image of the area scanned.

*The viewpoints expressed in this paper are those of the authors and not necessarily those of the Technology Assessment Board or its individual members.

**This paper draws here and throughout on information from a report on computed tomography scanners being prepared by the Office of Technology Assessment, Congress of the United States, Washington, D.C.

Because a CT scanner makes a composite image, it has definite advantages over conventional X-ray. Reconstructing narrow cross sections prevents overlapping organs from obscuring one another in images. CT scans also detect small differences in density among adjacent structures. These two attributes make CT scans especially helpful for visualizing soft, low density tissues such as the brain.

Tomographic devices similar to the CT scanner were constructed in the United States during the early 1960s, but they were not noticed by the medical community. The first CT scanner was developed in 1967 by G. Hounsfield, an engineer at Emitronics, Ltd., (EMI), in Britain. In 1971, the British Department of Health supported the installation of a prototype scanner in London, and in June 1973, the Mayo Clinic installed the first scanner in the United States. R. S. Ledley at Georgetown University Medical School later developed a model that scanned not only the head, but also the rest of the body. Marketed by Pfizer, the first CT body scanner became operational in early 1974. Thereafter, acceptance and diffusion of CT scanners proceeded rapidly.* By May 1977 there were at least 400 CT scanners installed in the United States.† Although installed machines are approximately equally divided between head and body scanners, body scanners now account for most new purchases.

Diffusion

The rate of installation of CT scanners in the United States has increased steadily over time. The diffusion curve in Figure 1 falls into three periods, each with a higher rate of installation. The first period began in June 1973 with the installation of the first head scanner at the Mayo Clinic. From that date through September 1974, the rate of installation was less than five per month. Between October 1974 and June 1975, the rate increased to just below ten per month. The third and most recent period for which the data are complete began in July 1975 and extended through September 1976; an average of 19 scanners per month were installed during that period. Nationally, the ratio of CT scanners to million population was 1.5 in August 1976. Data since then are incomplete. When all of the 652 machines that were installed, approved or ordered as of August 1976 become operational, the national ratio will double to 3 scanners per million population.

The rate of installation will probably continue at more than 20 scanners per month in the immediate future. Existing manufacturers such as EMI and Ohio Nuclear increased their production schedules during 1976 because they had persistent backlogs of unfilled orders.[1] Longer-term rates of orders

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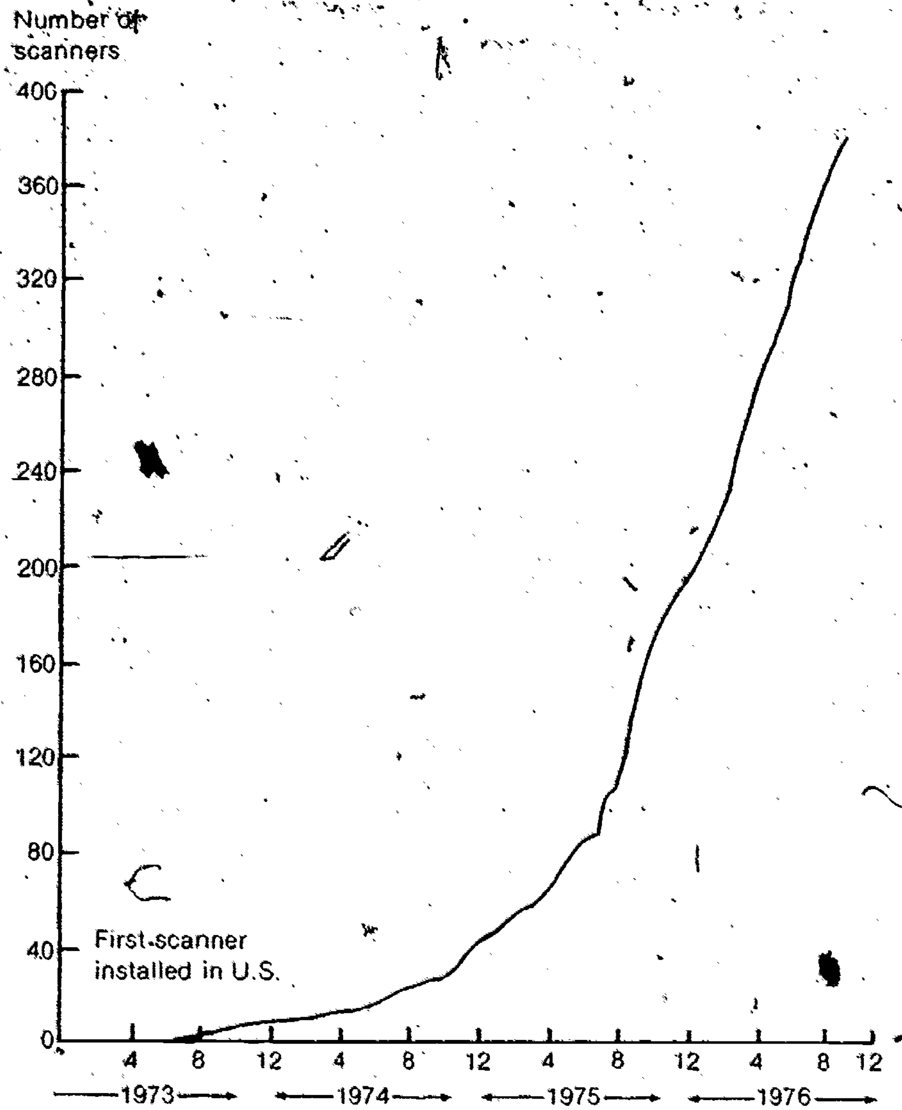
* Emitronics manufactured the first CT scanner installed in the United States and 92 percent of all head scanners known to be installed by May 1977. However, Ohio Nuclear accounted for 64 percent and Emitronics only 12 percent of installed body scanners.

† In May 1977, the Office of Technology Assessment was able to document 401 operational CT scanners. Approximately 380 of those were operational by the end of September 1976, and, as can be seen in Figure 1, approximately 20 scanners a month were being installed in 1976. Lags in reporting of scanners make it impossible to obtain a completely up-to-date number. On the basis of 380 scanners as of September 1976, and an installation rate of 20 per month, we estimate 540 scanners operational by June 1, 1977.

Figure 1

Cumulative number of CT scanners in the United States



Source U.S. Congress, Office of Technology Assessment and installations are not clear. Additional companies are planning to enter the market, and their entry will increase productive capacity. But the number of new orders in the first half of 1977 fell from the high of 1976, and one estimate predicted 200 new orders in 1977 compared to more than 400 in 1976.[2] In fact, orders during 1975 and 1976 may have been abnormally high. Providers anxious about implementation of the 1974 planning act may have rushed to place orders before they would have to be reviewed by planning agencies. Experience during 1977, then, may represent a temporary adjustment before a rise to a more stable growth rate.[2]

Many factors that might have constrained the diffusion of CT scanners have been absent or weak. Medical personnel, both physician specialists and technicians, require minimal training to operate a CT scanner; they already possess the basic knowledge, and their skills may be refined through practice. Radiation and contrast involve some risks, but CT scanning is not so obviously dangerous or painful for patients as certain alternatives. CT scanning also appeals to physicians because it gives them more information for making diagnoses. It therefore conforms with medical education, which teaches physicians to refine diagnoses as much as possible.

Unlike the early diffusion of most other medical equipment, that of CT scanners has been closely documented, even though by August 1976 less than 5 percent of community hospitals had one installed. In contrast, the diffusion of other medical technologies with high fixed costs has usually been charted only after 10 percent of hospitals have adopted them.[3] However, since the 10 percent level of adoption of CT scanners appears to be approaching quickly, there is some basis for comparing the diffusion of other medical technologies with that of CT scanners. In fact, the pattern of adoption of scanners resembles that of other technologies with high fixed costs in several ways.

It was the largest hospitals that initially adopted new technologies such as cobalt therapy, electroencephalographs, and intensive care facilities.[4] CT scanners are also following this pattern; 44 percent of community hospitals with 500 beds and over have a CT scanner, and 47 percent of hospital-based scanners are in the 5 percent of hospitals with 500 beds and over. Like other large hospitals, those affiliated with medical schools have been among the first to acquire equipment requiring large initial outlays,[5] a tendency borne out with CT scanners. Of the 113 accredited medical schools, 79 percent have a major affiliation with a hospital owning a scanner.[6]

The ratio of physicians to population has been observed to be positively associated with a demand by hospitals for technology with high fixed costs.[5] However, a test of this hypothesis showed little correlation between physician to population ratios and CT scanners to population ratios.*

* Kendall's coefficient of $\tau = .04$. Possible values of τ are -1 (inverse relationship), 0 (no relationship), and $+1$ (identity). It would be useful to retest the hypothesis with a different statistical technique; a different geographical division, for example by Standard Metropolitan Statistical Area; and ratios of medical specialists to population in lieu of all physicians.

Table 1
Distribution of CT scanners by type of facility[3,7,a]

Type of facility	Percent of all facilities	Number of facilities with CT scanners	Percent with CT scanners	Number of CT scanners
Community Hospitals	100%	297	5.1%	316
(Number of beds)				
0– 99	50	6	0.2	6
100– 199	23	11	0.8	11
200– 299	12	43	6.3	43
300– 399	6	52	13.8	53
400– 499	4	57	24.8	58
500– 599	5[b]	42	44.0[b]	47
600– 699	—	31	—	33
700– 799	—	14	—	14
800– 899	—	13	—	16
900– 999	—	10	—	12
1000–1099	—	7	—	8
1100–1199	—	6	—	7
1200–1299	—	1	—	4
1300 and over	—	4	—	4
Federal Short-Term General Hospitals	100	6[c]	1.8	9
All U.S. Hospitals	100	303	4.2	325
Offices & Clinics	—	74	—	76
Total	—	377	—	401

[a] *Additional sources:* American Hospital Association and Office of Technology Assessment. Includes scanners known to be installed by May 1977.

[b] For hospitals with 500 beds and over. Hospitals with 1,000 beds and over accounted for 0.5 percent of all community hospitals in 1975, and 64 percent of these have a CT scanner.

[c] Includes six Federal hospitals: Veterans' Administration, Boston, Mass., 291 beds, 1 scanner; Veterans' Administration, Durham, N.C., 501 beds, 1 scanner; Veterans' Administration, Indianapolis, Ind., 725 beds, 1 scanner; Veterans' Administration, Palo Alto, Calif., 1,381 beds, 1 scanner; National Institutes of Health, Clinical Center, Bethesda, Md., 511 beds, 4 scanners; and Naval Regional Medical Center, San Diego, Calif., 1,356 beds, 1 scanner.

Efficacy and safety

The rapid and widespread diffusion of CT scanners has pointed up shortcomings of existing policy. CT scanners were diffused throughout the medical care system before their efficacy and safety were completely assessed. Although much clinical experience has now accumulated, no systematic assessment has been made of the benefits of CT scanning and the circumstances under which it should be used. No federal agency has a mandate to require, fund, or conduct large-scale clinical trials meeting high standards of experimental design that could help determine the ultimate position of CT scanning in the practice of medicine.

Both the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) have been involved in evaluating CT scanners. NIH has been funding and conducting clinical trials of their diagnostic accuracy, and before diffusion of the scanners, FDA's Bureau of Radiological Health considered their safety. The Medical Devices Amendments of 1976 later gave FDA the responsibility for evaluating both the safety and efficacy† of devices;

† The law uses the term *effectiveness*.

FDA has classified the CT scanner as a Class II device, a classification that means that efficacy will be evaluated in terms of performance standards. The Bureau of Medical Devices is now developing such standards, which are expected to be only technical in nature.

Thus, federal efforts have been limited to technical considerations and diagnostic accuracy. Knowledge of the advantages of CT scanning and its role in medicine is being amassed in ways typical of other medical technologies, through clinical experience, publications, conferences, and reports of colleagues.

Definition and assessment of efficacy

Efficacy is the potential benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. So defined, it is an abstract concept projecting the results that a technology might achieve. Efficacy is more than a simple consideration of potential benefits. No technology is beneficial in the absolute; it is beneficial only when used in an appropriate manner—for a defined population, for given medical problems, and under certain conditions of use. Well designed studies of efficacy consider all of these factors.

The term *benefit* refers to the usefulness or value of the technology. For preventive or therapeutic technologies, benefit refers respectively to the potential for preventing disease or for improving the health of a patient. But for diagnostic technologies such as the CT scanner, defining efficacy is more complex because the technology itself cannot directly affect the physical health of patients. The question then arises whether efficacy is limited to diagnosis, or whether it depends on the availability of an efficacious therapy.

Several formulations of efficacy for diagnostic technologies have been developed. Fineberg and his coworkers have designed one in terms of five levels:[8]

1. Technical capability. Does the device perform reliably and deliver accurate information?
2. Diagnostic accuracy. Does use of the device permit accurate diagnoses to be made?
3. Diagnostic impact. Does use of the device replace other diagnostic procedures, including surgical exploration and biopsy?
4. Therapeutic impact. Do results obtained from the device affect planning and delivery of therapy?
5. Patient outcome. Does use of the device contribute to improved health of the patient?

Another formulation of efficacy for diagnostic X-ray technologies has been suggested in a study sponsored by the American College of Radiology: Efficacy-1, the information content of the procedure; Efficacy-2, the use of the diagnostic information in prescribing treatment or directing further diagnostic information-gathering; and Efficacy-3, the expected value of diagnostic information to the health of the patient.[9]

Evidence of efficacy of CT scanners

Efficacy has been more thoroughly assessed for CT scanners than for many other medical technologies at a similar stage of development and use. However, the evidence has not come from well designed, prospective clinical trials, but, as is typical for medical technologies, from observations of clinical experience. Moreover, diffusion of CT head scanners became widespread before much of this information had accumulated. Until June 1975, only 13 clinical papers had been published on head scanning, but almost 100 scanners had been installed.[10]

The results of clinical experience are presented here without necessarily endorsing the manner in which they were obtained. For purposes of discussion, the evidence is arranged according to the five levels of efficacy in the Fineberg formulation.

CT scanners have been well assessed for *technical capability* and are known to perform reliably and to deliver accurate information, as demonstrated by use of special test specimens and autopsy material.

At the level of *diagnostic accuracy*, head scanning has been more carefully studied than body scanning. More than 30 studies have presented data by diagnosis on diagnostic accuracy of head scanners.* The studies are accumulations of clinical experience, not carefully designed, large-scale clinical trials. Diagnoses are confirmed in these studies by other diagnostic techniques, by surgery, or by autopsy. Available evidence indicates that CT head scanning is quite accurate for neurodiagnosis, with greater than 90 percent accuracy. False negative diagnoses occur in only 5 to 10 percent of all tests, with higher false negatives in stroke diagnoses than in diagnoses of brain tumors. Recent studies also show a low rate of false positives. For example, Clifford and his coworkers found 3 false positives in 297 patients, for a rate of 1 percent.[11] Preliminary evidence on diagnostic accuracy of body scanning suggests that it can provide accurate diagnoses of tumors and cysts and a number of lesions in the organs of the abdomen, particularly in the kidney and liver.*

At the level of *impact on the planning or delivery of diagnostic services*, some evidence has been obtained for head scanning, but very little for body scanning. For the head, other neurodiagnostic procedures were in use prior to the development of CT scanning. The most common were cerebral arteriography, pneumoencephalography, and radionuclide brain scanning. In cerebral arteriography, dye is injected into the blood stream, and standard X-rays of the skull are taken to image the blood vessels. During pneumoencephalography, air is injected into the spinal canal, causing the ventricles of the brain to be visible on standard skull X-ray. Radionuclide brain scanning is a procedure in which radioisotopic material is injected into the blood stream and the head "scanned" by a camera that detects and records the radioactivity.

In Table 2 these three procedures are compared with CT scanning for accuracy, risk, and utilization, with estimations of the effect that the CT

* The Office of Technology Assessment report on CT scanners will continue a complete list of references.

Table 2
Comparison of CT head scanning with other neurodiagnostic procedures[a]

Procedure	*Diagnostic accuracy*[b]	*Approximate annual number of procedures in United States, 1976*	*Safety compared to CT scanning*	*Usable on out-patients*	*Estimated effect of CT scanning on utilization*
CT scanning	High—generally 80-90%	855,400-987,000	—	Yes	—
Arteriography	Similar to CT	100,000-350,000[c]	Riskier	No	−20% to 0[d]
Pneumoencephalography	Similar to CT	25,000-50,000[e]	Riskier	No	−40% to −75%[f]
Radionuclide scanning	Inferior to CT	2,000,000	Similar	Yes	−90% to +15%[g]
Skull X-ray	Used for purposes different from CT; inferior when compared	4,000,000[h]	Similar	Yes	Little or no effect

[a] Estimates of Office of Technology Assessment unless noted.

[b] Numbers in this column are not strictly comparable. Arteriography is often used after diagnosis of a brain tumor, for example, to demonstrate its extent and vascularity. Arteriography and pneumoencephalography are seldom used with stroke. Nonetheless, on the basis of published studies, the comparisons are basically valid.

[c] Low figure is for 1975 in Podell.[13] High figure is from Demand for Computed Tomography.[14]

[d] Baker, Campbell, Houser, et al.[15] reported −20 percent and Buenger and Huckman[16] reported +0.05 percent.

[e] Figures are for 1973 and 1975. In 1976, CT head scanning had a great impact on the number of pneumoencephalograms done, and estimates for 1976 are not available. Low figure is for 1975 in Podell.[13] High figure is a national projection of a 1973 survey in southeastern Pennsylvania as reported by Regional Comprehensive Health Planning Council.[17]

[f] Baker, Campbell, Houser, et al.[15] reported −40 percent and Knaus, Schroeder and Davis[18] reported −75 percent.

[g] Knaus, Schroeder, and Davis[18] reported +15 percent and New[19] reported −90 percent.

[h] Figure is for 1970.[20]

scanner has had on their use. As can be seen in the table, CT head scanning is as accurate as arteriography and pneumoencephalography, but involves less risk. An additional advantage of CT scanning is that it can be used on outpatients. CT scanning is considerably superior to radionuclide scanning and skull X-ray when used for the same purposes. To some extent, however, the procedures are complementary. Arteriography or pneumoencephalography may find an abnormality not seen on CT scanning. Each of the other procedures also has advantages for particular abnormalities.

Table 2 also shows the impact of CT head scanning on the other diagnostic procedures as reported by institutions having scanners. Use of pneumoencephalographic procedures fell dramatically after introduction of CT scanning, but the total prior to CT scanning was small. Modest decreases in arteriography and radionuclide scanning also occurred. The small size of these reductions may stem from three sources: not enough experience has accumulated to allow physicians to have confidence in CT scanning as a single diagnostic method; there is a general attitude that CT scanning complements other procedures; and the system has no mechanisms to ensure that new technologies, once available, will replace the old. At Cleveland Clinic, which had one of the first CT head scanners, radionuclide brain scanning has fallen to 15 percent of the pre-CT total. Cleveland Clinic also anticipates eliminating the standard skull X-ray for 80 percent of its patients in 1977.[12]

Several recent papers have indicated that CT head scanning can make other, dangerous diagnostic or therapeutic procedures unnecessary.[21,22] In one study, for example, a London hospital found a sharp reduction in the need for exploratory surgery in head trauma following introduction of CT scanning. In the year before its introduction, exploratory surgery was performed on 33 percent of patients with head trauma; in the following year on only 2 percent.[23] No attempt was made, however, to ensure that the different groups of patients studied were comparable.

At the fourth level of efficacy, *impact on the planning or delivery of therapy*, little is known. One pilot study found that therapeutic plans were changed as a result of CT head scanning in about 15 percent of patients scanned.[8] On the other hand, Larson and his coworkers studied cohorts of patients with stroke before and after introduction of CT head scanning and found no differences in therapy after introduction of the scanner, although the cost of diagnosis was increased.[24] Again, whether or not the patient groups were comparable is not known. No information on impact of therapy is available for the body scanner.

Thus far there appear to be no studies providing evidence that CT head or body scanning contributes to improved *patient outcome*. The only published study compared the experience in a London hospital before and after CT scanning was introduced as a routine technique for patients presenting with acute head trauma. In that study, mortality was unchanged, but other indicators, such as morbidity, were not studied.[23] One might accept reduced exploratory surgery as presumptive evidence of improved outcome.

The use of contrast injection raises additional questions of efficacy. Overall, about 60 percent of patients given head scans have contrast material injected.[14,25] The contrast material increases the density of blood to X-ray and makes certain structures more visible on a CT scan. Contrast injection is time-consuming, adds considerably to the cost and price of CT scanning, and entails some risk to the patient. Many lesions can be seen better on contrast-enhanced than on unenhanced scans; such information may be useful for surgical patients. On the other hand, two large studies found that use of contrast revealed lesions invisible on regular head scans in only two to five percent of all patients.[26,27] Recent articles have begun to specify appropriate uses of contrast.[28] For example, French and Dublin found contrast to be of little use in cases of trauma to the head.[29]

Safety of CT scanners

The potential benefits of CT scanning must be weighed against its risks. Safety, like efficacy, can be assessed by well designed clinical trials or by studies of clinical experience. Evaluations of safety involve factors similar to those for efficacy: risk, defined population, medical problem, and conditions of use.

Like other radiological devices, CT scanners emit X-rays, a form of potentially dangerous ionizing radiation that can cause cancer, leukemia, and genetic changes. Early reports indicated that the EMI head scanner exposed a patient to about 1 to 2.5 rads, less than other neurodiagnostic techniques using X-ray.[30] However, recent articles indicate that radiation exposure is higher than earlier thought. Horsely and Peters examined the factor of scattered radiation from adjacent scans and found that with 3 scans, the peak exposure with the EMI scanner is 4 to 5 rads.[31] The Bureau of Radiological Health of the Food and Drug Administration has stated that machines in use cause exposure as high as 30 rads,[32] and a recently published article reported an exposure of 21 rads from use of the Ohio Nuclear prototype head scanner.[33] On many machines, increasing the radiation dose to make the image clearer is possible by the simple adjustment of a switch.

Reaction to contrast material is another risk. In practice, mortality from injection of contrast agents ranges from 1 death in 13,000 examinations to 1 death in 50,000 examinations. This rate may be contrasted with a rate of approximately 1 in 1,500 cases in angiographic examinations.[12] Thus, CT scanning is safer than some other diagnostic technologies that may be used for the same purpose.

Patterns of use

Current federal policy does not link development of appropriate standards of use for CT scanning with efficacy. Individual Professional Standards Review Organizations (PSROs) might base their standards on efficacy if this information were available. Lack of information on circumstances of use has so far precluded the development of such standards.

The Health Standards and Quality Bureau, Department of Health, Education, and Welfare, administers the PSRO program, a federally mandated system of independent peer review organizations in 203 separate geographic areas throughout the nation. Each PSRO establishes standards for the appropriate use of medical services, including diagnostic procedures, in its own geographic area. No PSRO has yet issued guidelines for CT scanning.

However, a body of information has developed on diagnoses of patients who have received CT head scans. The most common diagnoses are mass lesions (mostly tumors), cerebrovascular disease (stroke, hemorrhage, and aneurysm), and diseases with enlargements of the ventricular space of the brain (hydrocephalus and cerebral atrophy). Institutions have reported that from 7 to 30 percent of patients scanned had brain tumors, 6 to 29 percent atrophy or hydrocephalus, 8 to 17 percent infarction (stroke), and 2 to 11 percent hemorrhage or aneurysm. Most of the remaining examination results were reported as normal.[14] One study indicated that in institutions surveyed, about 50 percent of scan results were normal, with some institutions running as high as 80 to 90 percent.[14] Little experience has been reported for body scanning.

Although information on diagnoses exists, the critical question of the appropriate indications for head scanning has not been effectively addressed. Ideally, a patient is scanned when there is a reasonable likelihood that useful information about the patient's condition will be found.

Few institutions have reported indications used for head scanning. In two large neurological referral centers, CT head scans were ordered for patients because of suspected mass lesions in 30 percent of scans, vascular abnormalities (such as stroke) in 10 percent, trauma in 5 percent, suspected optic lesions in 5 percent, suspected hydrocephalus or shunts in 5 percent, and symptoms such as headache, confusion, seizure, or dementia in 23 to 30 percent (indications for other patients were not given).[14]

Alderson and his coworkers reviewed the experience of one institution and found that of 490 patients scanned for neurological examination, 195 had abnormal results (38 of them were diagnosed as having strokes), and 295 had normal results. Of those with normal results, 67 had headache only, 54 had seizures, 60 had mental deterioration, and the remaining 114 had miscellaneous complaints.[35]

CT head scanning is commonly used on patients whose only symptom is headache. Two studies have examined the results for such patients. Alderson and his coworkers found that 67 otherwise normal patients with headache had only 3 abnormal scans, and that these were of little clinical importance.[35] Carrera and coworkers reviewed the experience of 53 patients whose chief complaint was headache, but who had no other abnormal neurological findings, and found no abnormal CT examination results.[36]

Another common use is for patients with head trauma. French and Dublin reported experience in 1,000 consecutive patients with head injuries who were scanned.[29] Twenty-seven percent of the patients were alert and had normal neurological examination results; only 13 percent in this group had abnormal scans, and none required surgery.

Alderson analyzed results in 295 patients with complaints but no focal findings* on neurological examination; 205 scans (70 percent) showed normal conditions.[35] If "brain softening" is excluded, only 15 (5 percent) had an abnormality. A symptom that did seem to indicate common abnormalities was the acute onset of seizures. In 28 such patients, four had lesions, two of them tumors.

Planning

The absence of clearly defined conditions for using CT scanners has handicapped planning activities. Planners operating under the authority of federal and state legislation are charged with controlling the installation of equipment such as CT scanners so that it conforms to need. To determine need and thus the appropriate number of scanners for an area, planners require information about the population potentially benefiting from CT scanning, the medical conditions it can diagnose, the symptoms prompting its use, and the place of scanning in the work-up of a patient, including how CT scanning might complement or replace other diagnostic procedures.

* Focal findings are objective abnormalities, such as depressed reflexes on one side of the body, that indicate nervous system disease

The National Health Planning and Resources Development Act of 1974 requires that each state establish a Certificate-of-Need program to review the appropriateness of facilities and services in order to be eligible for certain federal health funds after 1980. The law, now being implemented, covers expenditures over $150,000. Federal funds that will be affected are those available under the Public Health Service Act, the Community Mental Health Centers Act, and the Alcohol Abuse and Alcoholism Act. By May 1977, 35 states had enacted Certificate-of-Need laws to review proposed changes in facilities, equipment, and services. In addition, Section 1122 of the Social Security Act allows the Secretary of Health, Education, and Welfare to withhold federal funding for depreciation, interest, and return on equity capital for equipment considered inconsistent with a state's health plan. Section 1122 covers purchases over $100,000 and hence generally applies to CT scanners. Currently, 38 states have contracts with HEW to conduct reviews under Section 1122.

Operating under these laws in the absence of information on efficacy, planning agencies have devised various methods to estimate the desired number of CT scanners. One approach involved choosing an arbitrary number as a ratio of scanners to population. Resulting ratios varied greatly: Indiana suggested 1 scanner per 100,000 population; and Alabama, 1 per 500,000 population.[37, 38] One CT scanner for every 200-bed hospital was another proposed guideline.[39]

Planners have also based estimates on the incidence and prevalence of diseases for which CT scanning was being used. The frequency of certain carcinomas and neurological disorders led Kentucky to conclude that 46,000 people in the state need CT scans.[40] However, the identification of diseases suitable for CT scanning sidesteps the fundamental question of appropriate indications for use.

Other planners estimated need by comparing utilization of CT scans to that of other diagnostic procedures, usually radionuclide scans, arteriograms, and pneumoencephalograms. A formula used by the South Central Pennsylvania Health Planning Council projected annual CT scans based on 90 percent of the number of radionuclide scans, 75 percent of pneumoencephalograms, and 20 percent of arteriograms being performed.[39] But using alternative diagnostic procedures as a guideline reflects early practice patterns, which developed without studies related to efficacy.

Since the National Health Planning Act has not been in effect very long, planners may not have had time to affect the course of scanner installation. Other federal and state laws have been in effect longer and, taken together, would be expected to explain some of the differences in the distribution of CT scanners. But the existence of planning legislation does not explain variation among states.

Throughout the United States, only the District of Columbia lacks guidelines or legislation applying to scanners (Table 3). Missouri has statewide planning criteria for CT scanners. In June 1976, the District of Columbia and Missouri had two of the ten highest concentrations of CT scanners. But of the other eight, Nevada, Colorado and Florida had both

Table 3

Planning, legislation and distribution of CT scanners by state, region and population[41]

Region or state	Number of CT scanners: Installed	Number of CT scanners: Installed plus committed	CT scanners per million population: Installed	CT scanners per million population: Installed plus committed	Existence of legislation: Certificate-of-Need	Existence of legislation: Section 1122 agreements
New England	17	24	1.4	2.0		
Maine	1	3	1.0	2.8		x
New Hampshire	1	1	1.2	1.2		x
Vermont	0	1	0	2.1		x
Massachusetts	11	12	1.9	2.1	x	
Rhode Island	1	1	1.1	1.1	x	
Connecticut	3	6	1.0	1.9	x	
Middle Atlantic	35	79	.9	2.1		
New York	17	41	.9	2.3	x	x
New Jersey	2	12	.3	1.6	x	x
Pennsylvania	16	26	1.4	2.2		x
East North Central	50	134	1.2	3.3		
Ohio	16	36	1.5	3.4	x	x
Indiana	4	15	.8	2.8		x
Illinois	15	49	1.3	4.4	x	
Michigan	7	17	.8	1.9	x	x
Wisconsin	8	17	1.7	3.7	x	x
West North Central	30	48	1.8	2.9		
Minnesota	9	10	2.3	2.5	x	x
Iowa	1	7	.4	2.4	x	x
Missouri	13	17	2.7	3.6		
North Dakota	1	2	1.6	3.1	x	x
South Dakota	1	2	1.5	2.9	x	
Nebraska	1	5	.6	3.2		x
Kansas	4	5	1.7	2.2	x	
South Atlantic	49	99	1.4	3.0		
Delaware	0	2	0	3.4		x
Maryland	3	4	.7	1.0	x	x
District of Columbia	2	10	2.9	14.2		
Virginia	5	14	1.0	2.8	x	
West Virginia	0	5	0	2.7	x	x
North Carolina	4	4	.7	1.0		x
South Carolina	2	5	.7	1.8	x	x
Georgia	6	17	1.2	3.4	x	x
Florida	27	38	3.2	4.5	x	x
East South Central	18	36	1.3	2.6		
Kentucky	3	5	.9	1.5	x	x
Tennessee	7	17	1.7	4.0	x	
Alabama	6	11	1.6	3.0	x	x
Mississippi	2	3	.9	1.3		x
West South Central	30	59	1.4	2.8		
Arkansas	3	5	1.4	~~2.4~~	x	x
Louisiana	5	11	1.3	2.9		x
Oklahoma	3	7	1.1	2.5	x	x
Texas	19	36	1.5	2.9	x	

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Table 3—Continued

Planning, legislation and distribution of CT scanners by state, region and population[41,a]

Region or state	Number of CT scanners: Installed	Number of CT scanners: Installed plus committed	CT scanners per million population: Installed	CT scanners per million population: Installed plus committed	Existence of legislation: Certificate-of-Need	Existence of legislation: Section 1122 agreements
Mountain	19	39	1.9	4.0		
Montana	0	2	0	2.7	x	x
Idaho	3	4	3.6	4.8		x
Wyoming	0	0	0	0	x	x
Colorado	4	12	1.6	4.6	x	x
New Mexico	2	2	1.7	1.7		x
Arizona	5	8	2.2	3.5	x	
Utah	3	4	2.4	3.3		x
Nevada	2	7	3.3	11.5	x	x
Pacific	69	134	2.4	4.7		
Washington	5	6	1.4	1.7	x	x
Oregon	3	6	1.3	2.6	x	x
California	60	119	2.8	5.5	x	
Alaska	0	NA[b]	0	NA		x
Hawaii	1	3	1.1	3.4	x	
TOTAL	317[a]	652	1.5	3.0	35	37

[a] *Additional source:* Office of Technology Assessment. Statistics are current as of August, 1976, and are fairly complete through May, 1976, but there were 401 CT scanners installed by May, 1977. Laws are current as of July, 1977. Population data were provisional as of July 1, 1976. Committed refers to CT scanners already ordered and approved by local Health Systems Agencies. Four CT scanners at the National Institutes of Health are excluded from Maryland, but included in Total.

[b] Not available.

a Certificate-of-Need law and a Section 1122 agreement, and the remaining five states had either one or the other covering CT scanners.[42]

Among the ten states with the lowest ratios, Mississippi, New Hampshire, New Mexico, and North Carolina did not have a Certificate-of-Need law in June 1976. Neither did Wyoming, the only state without a scanner. However, these five states all had Section 1122 agreements.[42]

Of the 30 states with Certificate-of-Need laws in June 1976, the laws of at least four did not cover CT scanners. Those of Georgia and Illinois did not cover purchases of equipment; Ohio's law, which had not been implemented, did not specify coverage; and California's initial law covered only beds.[42]

Since fall 1976, a new Certificate-of-Need law in California has covered purchases of equipment such as CT scanners, but it provides for exemption of equipment already ordered. Once all committed scanners are installed, the concentration of scanners in California will double from 2.8 to 5.5 per million population. The state will then have the third highest ratio in the nation. The large number of orders suggests that providers anticipated the legal change and placed orders quickly before the law applied to CT scanners. These orders occurred despite the existence of a Section 1122 agreement.

Specific provisions of laws illustrate an additional shortcoming of present policies. Existing laws allow Certificate-of-Need regulations to be circumvented by installation of a scanner in a setting not subject to review. Section 1122, the 1974 planning act, and most Certificate-of-Need laws apply to hospitals and some institutions for ambulatory patients, but only Connecticut, Hawaii, Wisconsin, Minnesota, and Virginia have Certificate-of-Need laws that review equipment in private offices.[42,43] The investment tax credit gives providers another incentive to install scanners outside of hospitals. The credit lowers the effective cost of a CT scanner to physicians in private offices as opposed to nonprofit hospitals.

Locations outside of hospitals accounted for 76 CT scanners, 19 percent of the 401 scanners known to be operational in May 1977 (Table 1). A somewhat higher percentage of new scanners were installed in physicians' offices from June to September 1976: 27 percent compared to the 19 percent overall average. In addition, some CT scanners located in hospitals may be exempt from review. In June 1977, scanners located in hospitals, but owned or leased by physicians, numbered 61, or 10 percent of 637 scanners documented in a survey.[44]

A trend may be developing to broaden the coverage of state laws, if not federal. Massachusetts, New York, and Vermont are considering changes in their laws. These initiatives are often supported by third-party payers. Blue Cross-Blue Shield of Greater New York has spoken out in favor of its state's initiatives, as have the plans in Kansas City.[45]

Reimbursement

Links to planning

Federal reimbursement for CT scanning is linked to planning activities. However, gaps in the laws result in the exemption of many payments from regulation. As described above, Section 1122 of the Social Security Act makes part of the reimbursement under Medicare and Medicaid conditional on conformity with a state's health plan. But this section does not cover expenses of operation. For CT scanners, operating expenses account for 50 to 75 percent of the machine's technical expenses. And Section 1122 does not apply to payments for physician services and inpatient care connected with CT examinations.

The 1974 planning act strengthens the dependence of federal funding on planning approval. However, that law does not apply to programs that pay for services under the Social Security Act. In addition, Section 1122, the 1974 planning law, and most Certificate-of-Need laws do not apply to equipment in private offices and hence fail to cover all scanners.

Dependence on efficacy

Medicare as well as some individual Blue Cross and Blue Shield plans have made reimbursement for head and body scans conditional on a determination of efficacy. Federal Medicaid administrators, however, do not get involved in the issue of payment for new procedures; they honor state decisions.[46] The Bureau of Quality Assurance (BQA) (Health Standards and Quality Bureau after the 1977 HEW reorganization) evaluated CT scanning for Medicare when it was a new procedure in 1973. BQA had no formal mechanism for reaching a decision. The investigation consisted of questioning internal staff and outside experts about safety, efficacy, acceptance by providers, and stage of development, but BQA did not conduct studies itself. Medicare accepted BQA's recommendation to reimburse for CT head scans and not for body scans, which are still considered experimental.* [47]

BQA initially evaluated the efficacy of head scanning in 1973, when only EMI scanners were being marketed. Although other manufacturers began marketing scanners in 1974, Medicare reimbursement for CT scans was limited to EMI machines for three years, until October 1976.[47]

The evaluation of CT scanning illustrates the weakness of the policy assigning BQA the responsibility for evaluating the efficacy of new technologies. BQA had little information on which to make such judgments (especially in 1973) and neither the authority nor the resources needed to conduct efficacy studies. Although this function will be assigned to a different agency as a result of the recent reorganization in HEW, the fundamental problem will remain.

Method of reimbursement

In addition to problems connected with planning and efficacy, the federal reimbursement method itself has shortcomings. Problems arise from the use of retrospective reimbursement, which characterizes both Medicare's and Medicaid's payment of CT scans. These programs pay institutions for costs already incurred. They also pay physicians for charges after billing. As a result of these policies, the federal government has an open-ended commitment to finance services provided.

Charges and profits. Average total charges have exceeded estimated expenses for CT examinations by 39 to 229 percent (Table 4). Average total charges range from $240 to $260, and the extremes of estimated expenses from $79 to $173. Estimated annual profits from operating a CT scanner range from 11 to 65 percent of the original purchase price for a machine priced at $450,000, or from $51,000 to $291,000 per machine (Table 5).* Such

*The high boundary was constructed from high average charges and low average costs, and the low boundary from low average charges and high average costs. Of course, institutions with actual costs or charges outside these boundaries would have different profit rates. Bad debts were estimated at 10 percent of gross revenue, an average of estimates in the literature.

The percentage of CT examinations reimbursed on a cost basis is not clear. The physician portion, a charge, may be 50 percent or more of technical expenses. Scanners in ambulatory settings with both technical and professional portions paid by charges may account for a higher percentage of examinations than the number of office scanners would indicate. (See Evens and Jost.[25]) Expenditures based on costs include expenditures for hospital services by Medicare and Medicaid, half of the benefit expenditures of Blue Cross, and health service expenditures by the Defense Department and Veterans' Administration. Expenditures based on charges include expenditures for physician services by Medicare and Medicaid, the other half of the benefit expenditures of Blue Cross, all the benefit expenditures of Blue Shield and commercial insurance companies, and out-of-pocket expenditures of patients. These assumptions yield estimates of 30 percent of all personal health expenditures and 45 percent of hospital expenditures based on costs or direct provision of services.[48,49]

*In August 1977, a decision to reimburse for body scanning was expected shortly.

Table 4

Reported charges and estimated expenses for a CT head examination[13 14 25 37 38 50 51 52]

(Dollars)

(Annual number of examinations: 2,600–3,000)

	Range
Average total charge[a]	$240–260
Average total expense[b]	79–173
Average technical charge	174–200
Average technical expense	59–130
Average professional charge	53– 70
Average professional expense	20– 43

[a] Levels of charges take into account relative utilization of contrasted and uncontrasted scans.

[b] Average total expense differs from that drawn from the literature in Table 6. Half of the sources in Table 6 gave no estimates for professional expenses. Here the extremes of technical and professional expenses were added to produce a more realistic range, especially for the high estimate.

Table 5

Estimated average annual profits from a CT scanner, 1976[13 14 25 37 38 51 52]

(Dollars)

	Low	*High*
Average charge per examination	$ 240	$ 260
Average revenue[a]	222	210
(Number of examinations)	(2,600)	(3,000)
Total gross revenue	577,200	630,000
Less bad debts	–57,720	–63,000
Total net revenue	$519,480	$567,000
Average total cost per examination	180[b]	92[c]
(Number of examinations)	(2,600)	(3,000)
Total costs	$468,000	$276,000
Average profit	$ 51,480	$291,000
(Percent of original purchase price)	(11%)	(65%)

[a] Average revenue = .3 × average cost + .7 × average charge. Based on nonphysician expenditures by Medicare and Medicaid, personal health expenditures by Defense Department and Veterans Administration, and half of benefit expenditures by Blue Cross.

[b] Based on estimates by Evens and Jost[25] for technical cost and by Genesee Region Health Planning Council[38] for physician cost. Genesee's estimates were prorated to a rate of 2,600 annual examinations, $50 per examination.

[c] Genesee[38] estimates, with physician cost prorated for one radiologist, $33 per examination.

profits clearly provide an incentive for purchasing and using a scanner.

Some evidence suggests that charges have increased over time. From 1975 to 1976, 16 sites surveyed increased their charges for uncontrasted scans an average of 8 percent, and for contrasted and uncontrasted scans an average of 12 percent. Likewise, some increases occurred in the use of contrast, which carries a higher charge.[14]

There is no automatic tendency for fees to approximate expenses for CT scanning. Third-party payers such as the federal government generally accept charges and costs. Furthermore, a gap between the two does not deter utilization, which depends on decisions made by physicians, who order but do not pay for the scans. Individual patients have little effect on providers' prices; and little stimulus for charges to approach costs is provided by the market for CT scanning, which is characterized by neither perfect competition nor free entry of firms.

Regulatory activities and political considerations may moderate charges in the absence of other forces. In some areas of the country, state rate-review commissions are scrutinizing the difference between CT examination charges and costs. The Massachusetts Rate Setting Commission, for example, lowered allowable reimbursement rates for some hospitals and suggested that physicians' fees for CT scanning be reduced.[53 54] Especially since the restrictions experienced under the Economic Stabilization Program, providers have appeared somewhat cautious about cost and price increases in an attempt to avoid formal regulation.[55] Two hospitals that have lowered rates, Cleveland Clinic and Massachusetts General Hospital, attributed their decisions to higher profits than originally expected. Cleveland Clinic also noted that it had paid off the original cost of the scanner before reducing rates.

Costs. Federal reimbursement methods also give institutions no need to lower the expenses of performing CT examinations, since the government reimburses for expenses with little scrutiny. These providers have little incentive to devise cheaper ways to operate scanners, to bargain with manufacturers for lower purchase prices, or to lower the unit cost figure for examinations.

Depreciation or rental of the CT scanner itself is the largest single item in annual expenses. (Table 6). Original purchase prices of $380,000 to $585,000 translate into $80,000 to $117,000 annual depreciation under a straight-line depreciation schedule over five years, the term typical for CT scanners. Although eight years is usually used for equipment,[39] rapidly changing technology, that is, obsolescence, is cited as the basis for faster financial depreciation of scanners,* despite the opportunity to reduce the risk of obsolescence by leasing a scanner or updating older models. In 1976, EMI charged $100,000 to update its original brain scanner,[14] and the highest estimate of annual technical expenses includes, besides depreciation, $25,000 for the purchase of new equipment.[25] At least 26 percent of 96 institutions surveyed in 1976 leased their machines,[25] and the annual rental charge has been estimated as $76,000.*[50] This estimate suggests that rental of a scanner is less expensive than purchase and depreciation.

The purchase price of CT scanners has increased since their introduction. From 1973 to 1976 the price of the head scanner, most frequently sold by EMI, rose from $310,000 to $410,000, and from 1976 to 1977 the price of its body scanner rose from $475,000 to $530,000. However, these prices refer to a changing product; during that period EMI marketed three successive generations, each of which increased scanning speed or clarity. Furthermore,

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*Of course, depreciation, an allowance for equipment's wearing out, conceptually differs from obsolescence.

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*Only the estimate of technical expenses by Health Services Management, Indiana, included interest on a loan to purchase a machine. As an expense to the institution, interest should appear in all calculations involving a machine's purchase.

Table 6

Estimated annual expenses[a] of operating a CT scanner[13, 25, 37, 38, 39, 51, a]

Category	Range
	Thousands of dollars
Technical expenses	$177–337
Equipment[b]	76–117
Interest	0– 28
Maintenance on scanner	3– 40
Other maintenance and remodeling	0– 13
Nonphysician staff	36– 75
Supplies	15– 38
Indirect expenses	2–112
Other	0– 10
Professional expenses[c]	60–130
Total expenses[d]	259–379
(Number of examinations per year)	(2,600–3,828)
	Dollars
Average technical cost per exam	$ 59–130
Average professional cost per exam	20– 43
Average total cost per exam	86–126

[a] Buenger and Bass[39] reported one hospital's experience. All other expenses are estimates.

[b] Straight-line, five-year depreciation except for rental estimate of $76,000 by Buenger and Bass.

[c] Based on one radiologist except for the highest estimate using 1.3 radiologist by Genesee Region Health Planning Council.[38]

[d] Not computed from average technical and professional costs. Obtained from sources half of which, including the one with highest technical expenses, made no estimate of professional expenses.

in 1974 and 1976, prices for EMI head scanners rose less than the Wholesale Price Index (WPI).[56, 57] In 1974, the WPI rose 19 percent and the price of an EMI head scanner 17 percent; in 1976, the WPI rose 5 percent and the price of an EMI head scanner 3 percent. Only in 1975 did the change in the price exceed the change in the WPI, 12 percent compared to 9 percent.

Future price movements are unpredictable. The theory of a learning curve[58] would predict lower average costs over time as manufacturers gain experience with the production process. To the extent that economies of scale exist, increased production levels would decrease average costs. Provided there is price competition, continued entry of new firms could result in price reductions over time. In addition to the six firms producing CT scanners in 1977, at least six others were developing machines for marketing in the United States.[56] However, changing technology could push price increases ahead of general inflation. Identification of new uses for CT scanning and consequent increases in demand could also shore up prices that might otherwise fall.

The average cost of performing a CT examination declines as a scanner produces more examinations per year (Table 7). This pattern occurs regardless of whether more examinations are performed during one shift, usually estimated at about 3,000 annual examinations, or through the addition of a second shift. Producing 3,000 instead of 2,000 examinations a year, for example, may result in lower average total costs of $86 instead of $126, a difference of 32 percent.[51] Likewise, with 5,500 annual examinations, which would require two shifts, average total costs may be 24 percent below the level with 3,000 examinations, or $78 compared to $102. Thus, a given number of CT examinations could be performed at less cost on a small number of scanners operating more intensively, rather than on a larger number operating less intensively.* However, in the present context, scanners operating at higher rates, and hence more efficiently, will not necessarily continue while the less used machines cease to be used. And federal reimbursement policies do nothing to encourage that result.

In fact, CT scanners are being used much below full capacity. A CT head scanner's rate of output apparently increases with time. According to data from 111 sites, output rose from 2,800 examinations during the first year's operation to 3,400 the second year and 3,600 the third year.[14] Higher profits than expected have been attributed to this phenomenon. Providers initially set charges on projections of about 2,000 annual examinations per scanner. But actual use was much higher, about 3,000.[53] Because average costs are lower at high rates of output, the average cost of an examination proved lower than expected and the difference between cost and charges wider.* Although a scanner's output appears to increase over time, even after three years operation was limited to approximately one shift per day. The experience with CT scanners therefore conforms to the observation that hospital equipment is typically used at only 50 to 70 percent of capacity.[5]

Net expenditures

As noted above, CT scanning may provide information similar or superior to that derived from some other diagnostic tests. It therefore has the potential to effect some reductions in expenditures by replacing other diagnostic procedures. Furthermore, compared to pneumoencephalograms and arterio-

Table 7

Estimated average cost of a CT examination at different rates of output[26 37 39 51]
(Dollars)

Cost per examination	Annual number of CT examinations per scanner												
	Rhode Island, 1975			Indiana, 1976				Evens and Jost, 1976				Genesee, 1975	
	1,000	2,000	3,000	1,500	2,500	4,500	7,500	2,080	2,600	3,120	4,160	3,000	5,500
Average technical cost	175	91	62	140	97	60	46	157	130	112	89	59	42
Average professional cost	72	36	24	—	—	—		—	—	—	—	43	36
Average total cost	247	126	86	—	—	—	—	—	—	—	—	102	78

[a] Straight-line 4-year depreciation has been changed to 5-year here

*In sparsely populated areas, access may dictate acquisition of scanners for operation at low levels of output.

*Self-referral, where the same physician both orders a scan and receives payment for it, does not appear to be a problem for CT scanning. At least 89 percent of all scanners are in hospitals or radiological offices where one physician orders and another performs a scan. However, hospital physicians are certainly aware that CT scans generate revenue and benefit the hospital financially.

grams, a CT scan subjects patients to less danger and discomfort and consequently does not require hospitalization. However, since federal reimbursement covers scanning for both hospitalized and ambulatory patients, it provides no stimulus for performing scans on an ambulatory basis whenever possible. On the contrary, excess beds or low occupancy rates in an area may foster hospital admission.

Of the estimated total expenditures associated with CT examinations performed in 1976, 32 to 45 percent resulted from hospital admissions (Table 8).* An estimated $189 to $206 million was spent on CT examinations themselves, and associated inpatient days and daily inpatient physician visits brought total expenditures to $278 to $377 million.** It is likely that more CT examinations could be performed on outpatients. Two surveys reported 51 to 46 percent of patients were scanned as inpatients, with ranges from 23 to 90 percent, and from 11 to 75 percent respectively.[16, 52]

In addition, present reimbursement methods, including those of the federal government, encourage additional procedures, not selection among them, even if the results are duplicative. Under fee-for-service and retrospective payment methods, more services generate more revenue for physicians and hospitals. Reimbursement incentives thus reinforce the training that physicians receive to refine diagnoses as much as possible. Patients generally defer to physicians' judgments in such cases.

After expenditures on procedures replaced by CT scans were deducted, net expenditures on CT scanning ranged from $180 to $388 million in 1976 (Table 8).* Substituting CT examinations for radionuclide brain scans, pneumoencephalograms, and arteriograms reduced expenditures an estimated $38 to $113 million. Predictions have been made that CT scanning will continue to replace other procedures. However, no budget or other framework requires providers to make choices among procedures. And reimbursement methods of the federal government and most other third-party payers lack any mechanism that stimulates physicians to choose among alternative procedures, such as CT scanning, pneumoencephalograms, and radionuclide scans.

The example of Kaiser-Permanente in Northern California provides an interesting contrast to prevailing reimbursement methods. Kaiser-Permanente receives for each enrollee a predetermined per capita payment that remains fixed regardless of the number of services provided. In Kaiser-Permanente's budget, additional CT scans add to expenses, but not to revenue. During 1976, Kaiser did not own a CT scanner, but ordered about 2,500 annual examinations from outside providers, at the rate of 1,900 examinations per million population for its 1.3 million members.[61] Under the assumption

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*Based on the mix of costs and charges from Table 5.

**These estimates assume that hospitals performed from 46 to 51 percent of their examinations on inpatients and that inpatients waited from 1.6 to 2.2 days for a scan.

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*The Kaiser-Permanente membership has fewer persons 65 years and over than California's population, 4.9 compared to 7.8 percent.[61]

Table 8

Estimated expenditures for CT scanning, 1976

(Thousands of dollars)

	Low	*High*
Based on costs and charges[a]		
Expenditures, all scanners	$188,744	$206,010
Hospital day expenses[b]	81,459	143,286
Inpatient physician charges[c]	7,917	27,853
Total expenditures on CT scanning	$278,120	$377,149
Based on charges only[d]		
Gross expenditures, CT examinations	$293,425	$426,199
Reduced expenditures	113,319[e]	38,336
Radionuclide brain scans	37,499	17,375
Pneumoencephalograms	53,944	8,790
Arteriograms	21,875	12,171
Net expenditures on CT scanning	$180,106	$387,863

[a] Based on the mix of costs and charges of CT examinations from Table 5 for 327 scanners, the number installed by June 1976.

[b] Based on 274 hospital scanners, 46 to 51 percent of hospital examinations for inpatients, a wait of 1.6 to 2.2 days, and adjusted hospital day expenses of $155.36.

[c] Based on 1 to 2 physician visits per hospital day by an internist charging $15.10 for a follow-up hospital visit.

[d] Based on charges, not costs, of procedures, except for hospital day expenses. See Appendix for calculations.

[e] Total due to rounding.

that 3,000 annual examinations have been the equivalent of one scanner, Kaiser-Permanente has been using 0.65 scanner per million population, roughly 23 percent of the California rate of 2.8 scanners per million population and 43 percent of the national rate of 1.5. Kaiser-Permanente's utilization of 1,900 CT examinations per million population was greatly exceeded by the estimated California rate of 8,400 examinations per million. Standardization for age would raise Kaiser's relative rates,* and Kaiser expects some rise in utilization after installation of its own scanner. Even with these qualifications, however, utilization under the Kaiser-Permanente system has been dramatically lower than that for the state or the country.

A complete cost-benefit analysis is needed to compare CT scans, arteriograms, pneumoencephalograms and radionuclide scans for specified medical conditions. Such an analysis would provide the bases now lacking for rational choice among different diagnostic tests. Clinical experience is accumulating, but medical symptoms for which CT scanning permits superior diagnosis remain ill defined. Moreover, CT scanning's place in a diagnostic work-up is undetermined. Should CT scanning be the primary diagnostic test for certain conditions or should it be used only to refine diagnoses? The estimated marginal cost of a CT examination falls below $50 at rates of output of 3,000 and above, much lower than the present average cost of about $100. These data suggest a need for extensive exploration into the costs and benefits of using CT scanning compared to alternative procedures.

* Based on charges, not costs, except for hospital days.

Conclusions

The large purchase price sets CT scanners apart from some other medical technologies to the extent that expenditures for services are higher in order to cover large fixed costs. The purchase price may also trigger Certificate-of-Need laws. However, this study of the CT scanner has called attention to several policy problems in medical care, problems that relate to new and old, expensive and inexpensive technologies alike.

Well designed prospective studies to demonstrate efficacy have not been conducted. Except for technical precision, no systematic determination was made before diffusion. Clinical experience has become the guide, but no public or private body is charged with collecting and analyzing data on efficacy. As with CT head scanning and now with body scanning, physicians gather information as best they can from their own practice, from colleagues and from publications. Further, no public or private body collects the available information and provides it to physicians and organizations needing it, such as planning agencies, PSROs, and third-party payers.

The absence of information gained from studies related to efficacy handicaps planning and peer review organizations. The desirable distribution, concentration and location of CT scanners depend on their intended use and substitution for pre-existing procedures, matters that hinge on efficacy. Without clear specifications, planners have resorted to previous utilization, a dubious indication of need or efficacy, especially in the early stages of diffusion. Nascent peer review groups also require data on appropriate circumstances of use to carry out their functions.*

In some instances, third-party payers have made reimbursement dependent on prior efficacy determination and planning approval. These policies have the potential to affect expenditures. However, as a result of the gaps in state planning laws and Section 1122, many payments for CT scanning are not covered. Even when such policies apply, their effect has been diluted by poorly defined standards and inadequate information for assessing efficacy. Furthermore, third-party payers have not, as a general rule, made reimbursement for a procedure conditional on efficacy; CT scanning is unusual in this respect.

By its reimbursement methods, the federal government in effect assumes an open-ended commitment to finance services. Whether reimbursement is based on costs or on charges, existing mechanisms do not encourage efficient performance of services such as CT scans. Furthermore, there is little incentive to weigh benefits and costs of alternative procedures and choose among them. Certificate-of-Need legislation and peer review can be seen as attempts to remedy the effects of perverse incentives that encourage additional, perhaps unnecessary, procedures. CT scanning, a diagnostic tool with little apparent risk to patients, has lent itself to being added in a work-up. The discomfort and danger associated with alternatives such as pneumoencephalograms and arteriograms may have accounted for the degree to which CT scanning has been substituted for these procedures.

Available data on CT scanners cover the very early stages of diffusion. Following the future diffusion of CT scanners would permit a longer view

Appendix

Calculation of net expenditures for CT scanning, 1976[13,14,16,17,18]
(Dollars)

	Low	High
Average charge, CT examination	240	260
Total examinations	(850,200)	(981,000)
Charges for all CT examinations	204,048,000	255,060,000
Hospital day expenses	81,459,287	143,286,042
Inpatient physician charges[a]	7,917,322	27,852,976
Total gross CT expenditures[b]	293,424,609	426,199,018
Reduced radionuclide brain scans	(139,000)	(139,000)
Charges	24,603,000	17,375,000
Hospital day expenses	10,797,520	0
Inpatient physician charges[a]	2,098,900	0
Reduced expenditures[c]	37,499,420	17,375,000
Reduced pneumoencephalograms	(35,750)	(16,250)
Charges	7,507,500	3,250,000
Hospital day expenses	38,878,840	5,049,200
Inpatient physician charges[a]	7,557,550	490,750
Reduced expenditures[d]	53,943,890	8,789,950
Reduced arteriograms	(22,500)	(22,500)
Charges	5,175,000	4,500,000
Hospital day expenses	13,982,400	6,991,200
Inpatient physician charges[a]	2,718,000	679,500
Reduced expenditures[e]	21,875,400	12,170,700
Total reduced expenditures	113,318,710	38,335,650
Total net expenditures on CT scanning	180,105,899	387,863,368

[a] Based on 1 to 2 physician visits per hospital day by an internist charging $15.10 for a follow-up hospital visit.

[b] Based on charges, not costs, of procedures, except for hospital day expenses: 327 machines as of June 1976 (274 machines in hospitals); output of 2,600 to 3,000 annual examinations per machine; 46 to 51 percent of hospital examinations on inpatients, an inpatient wait of 1.6 to 2.2 days, and adjusted hospital expenses of $155.36 per day.

[c] Estimated 35 percent decline in 1.1 million scans in 1973, from $125 to $177 per nuclide scan, and from 0- to 1-day stay for 50 percent of patients.

[d] Estimated decline of 65 percent. Estimates of the absolute number of pneumoencephalograms before CT scanning range from 55,000 or 5 percent of radionuclide brain scans in 1973 to 25,000. Also based on $200 to $210 per pneumoencephalogram, 2 to 7 days stay, and all patients as inpatients.

[e] Estimated decline of 20 percent, from $200 to $230 per arteriogram, from 2 to 4 days stay, and all patients as inpatients.

of such factors as charges and utilization patterns that relate to the cost and quality of medical care.

However, the shortcomings of federal policies illustrated by the case of CT scanning are not self-correcting. They promise to continue for head and body scanning and to recur for future medical technologies.

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Clinical chemistries: The high cost of low-cost diagnostic tests

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Introduction

A laboratory test is one of the least expensive diagnostic procedures a physician can order. This year, clinical laboratories will produce an estimated 5 billion tests* consuming approximately $11 billion in health resources.[1,2] Between 1970 and 1975, the number of laboratory tests increased at an average annual rate of 13.8 percent in hospital laboratories and 15.6 percent in independent (non-hospital) laboratories.[5-10] Clinical chemistries comprise 25 to 35 percent of all laboratory tests[2] and will account for approximately $3 billion of this year's health expenditures.

Studies of selected medical conditions and hospitals have found dramatic increases in use of chemistry tests and laboratory services. A study of patients hospitalized for myocardial infarction between 1939 and 1969 showed increases in chemistry tests with significant linear and quadratic regressions, indicating an accelerating growth over time.[11] Scitovsky[12] studied changes in prices and resource inputs for eight selected diseases. For maternity care, she found nearly a trebling of laboratory tests between 1951 and 1964; the resulting rise in costs almost offset savings due to a one day decrease in length of hospital stay and an increase in the number of women delivered without a general anesthetic. The increase in laboratory test costs for patients with perforated appendicitis more than offset the decreased average length of stay for that condition.[12] In a study of outpatient management of diabetes and hypertension, Komaroff found the cost of laboratory tests to be 1½–2 times the direct salary cost of manpower.[13] Griner's 1971 study of laboratory costs in a teaching hospital found chemistries to amount to approximately 40 percent of all laboratory charges and 10 percent of the total hospital bill; between 1965 and 1970, the number of chemistry laboratory tests increased by 95 percent.[14] Amador found a 13 percent average annual growth in laboratory volume at two hospitals between 1954 and 1974.[15]

The overall increase in use of laboratory tests masks variability in test growth for patients with different diseases.[12] There is also marked variability in laboratory utilization by different physicians treating similar patient populations. Schroeder found a 17-fold variation in laboratory use among

*The number of tests is an estimate, in part because of incomplete survey information and in part because of different definitions of a test. For example, it is sometimes unclear whether multiple determinations on a single sample count as one or multiple tests, and whether tests done for quality control are included.[2,3,4]

internists treating a homogeneous clinic population.[16] Marked differences in diagnostic test use also have been found for similar patients treated in different teaching hospitals[17] and in a teaching hospital compared to a community hospital.[18]

Development of new laboratory tests and technological innovations in laboratory instrumentation made possible and may have engendered the phenomenal growth in laboratory services. These technological developments also contributed to fundamental changes in the clinical laboratory industry. The first section of this paper will describe historical trends and the current structure of the clinical laboratory sector. The second section will summarize the reasons for the greater use of clinical chemistry tests. The third section will assess clinical chemistry tests in terms of costs and laboratory efficiency, technical quality, and clinical efficacy. Finally, conclusions and policy implications will be offered.

The clinical laboratory industry

There are nearly 15,000 clinical laboratories outside of physicians' offices in the United States,[5,6] consisting of approximately equal numbers of hospital and independent laboratories. While different observers agree that approximately 4.0 to 4.5 billion laboratory tests were done in 1975, the proportion they ascribe to independents ranges from 28 percent[5,6] to 37 percent[1] to 50 percent[2] of the total for hospitals plus independents. More than 180,000 persons were employed in the clinical laboratory industry in 1975.[5,6] Virtually all hospital labs[2,6] and nearly 80 percent of independent labs[5] do clinical chemistry tests. Fifteen percent of hospital labs[6] and 7 percent of independents[5] performed more than 500,000 tests in 1975; that same year, 35 percent of hospital labs[6] and 58 percent of independents[5] performed fewer than 50,000 tests. During the first half of the seventies, the trend was toward larger volume in both hospital and independent laboratories.[3,8] The markets for hospital and independent laboratories overlap to some extent. Approximately 15 percent of tests done by independents are for hospitals (many by specialized labs), and approximately the same proportion of tests done by hospitals are for outpatients.[10]

Prior to World War II, clinical laboratories had low volume and relatively high unit costs.[19] In general, pathologists ran hospital laboratories, and state-licensed medical technologists served the needs of private physicians. After World War II, the College of American Pathologists was organized, and this professional group exerted pressure to change salaried or other disadvantageous contracts into fee-for-test or other favorable arrangements.[19] Insisting that laboratory services were the practice of medicine and required a physician in charge, pathologists established laboratory services outside of hospitals. In the mid-1950s several state attorneys general declared that laboratory services were not the practice of medicine,[19] but the hold of pathologists persisted until 1969. Then, the Anti-Trust Division of the U.S. Attorney General's Office successfully obtained a consent decree condemning the College of American Pathologists' effort to restrict laboratory ownership. This, together with the development of relatively expensive automated equipment offering economies of scale to high volume operators, opened the way for publicly held corporations to enter the clinical laboratory business. By 1975, laboratory chains (more than 5 laboratories) held 9.5 percent of nonhospital labs, and owners of multiple labs (2 to 5) controlled another 10.9 percent.[5] The largest chain controlled less than three percent of the independent market and less than one percent of the total laboratory market.[1] In general, corporate laboratories fall into one of three categories: a group of small labs serving physicians directly; a very large-volume, central processing laboratory; or a reference lab doing specialized work.[19]

Clinical laboratories also support a rapidly growing segment of the chemical industry. Between 1969 and 1974, sales of chemical reagents for tests grew 21 percent per year, reaching $490 million in 1974.[20] Several large chemical firms market both analyzers and reagents, and one manufacturer estimated that a five year supply of chemicals for its auto-analyzer represented the same volume of sales as the original instrument.[20] Total sales of instruments in 1974 were $210 million, only 43 percent of the sales of reagents.[20] Laboratory supplies accounted for an additional $160 million.[20]

Technicon is the dominant manufacturer of automated clinical chemistry equipment, although a number of other manufacturers have made inroads. Technicon introduced the first automated chemistry analyzer in 1955, based on a continuous flow concept, and this was the only practical form of automation for the next decade. Further developments by Technicon culminated in 1966 in the SMA 12/60 (Sequential Multiple Analyzer), which could process 60 samples or 720 determinations per hour. That same year, Hycel introduced its MARK X discrete analyzer, which could perform tests selectively. To date, Hycel has sold more than 500 of its machines; Technicon has sold approximately 3,500 auto-analyzers, DuPont (entered 1970) more than 500, and Coulter approximately 125.* Other large companies which have marketed chemistry analyzers include Dow (entered 1969) and Union Carbide.[20] In April 1974, Technicon first offered its SMAC system (Sequential Multiple Analyzer plus Computer), which sells for approximately $240,000. This device allows the selection of 20 tests out of 24, requires no more than 0.45 cc of serum, and processes 150 samples or 3,000 determinations per hour. Since its introduction, approximately 450 SMACs have been sold.* A Swedish firm, Autochem Instruments, markets a $500,000 analyzer system with a 5,000 per day sample capacity.[21]

Reasons for increased use of clinical chemistry tests

Clinical chemistry tests may be used by physicians to screen patients for presymptomatic disease, to confirm or rule out a suspected diagnosis, or to monitor a patient's medical condition. Among the factors that may have contributed to the rise in use of tests are the following:

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* Information based on telephone interviews with representatives of the respective companies.

Advances in medical knowledge and discovery of new relations between biochemical abnormalities and pathology. While fewer than 100 laboratory tests were available in 1950, more than 600 are obtainable now.[22] An average of five new quantitative and semiquantitative tests were added each year between 1946 and 1975 to the Tables of Normal Values published in the *New England Journal of Medicine*.[15]

Increased insurance coverage and decreased out-of-pocket expense for patients. One survey of physicians' reasons for not ordering "ideally" desired tests found reluctance because of expense to the patient.[23] However, Medicare and Medicaid have provided dramatic increases in insurance coverage for the elderly and poor, and 80 percent of the population now have in-hospital laboratory costs covered. In addition, about half the population have out-of-hospital laboratory costs covered by insurance.[1]

Automation and increased convenience. Automation of laboratory analyzers provides economies of scale, and in some cases information systems help to speed test reporting and improve service to the physician. The convenience of using a hospital laboratory, with its proximity in case of questions, has grown with the addition of phlebotomy teams and computerized printouts.

Positive financial incentives for physicians, pathologists, and hospitals. Pathologists and hospitals both earn money from increased use of the laboratory. In many instances, pathologists work under percentage contracts with hospitals,[24] a practice encouraged by the College of American Pathologists.[19] Thus, the greater the laboratory revenues, the greater the pathologists' income. At the same time, hospital laboratories tend to earn income for hospitals, with charges generally believed to exceed costs by 15 percent[2] to 25 percent,[25] although the difference may be less in some hospitals.[24] This excess can be used to support other hospital departments. The physician caring for private patients can use an independent laboratory and, in most states, legally bill the patient for more than the laboratory charges. Even where laws forbid or discourage the practice, numerous ways exist to circumvent them.[19] In a 1976 report to Congress, the Comptroller General found physicians in five states who received from Medicare an average of 96 to 158 percent more than they had paid for laboratory tests.[26]

Training, personality, habit and social environment of physicians. Physicians are trained in teaching hospitals, where laboratory tests are introduced and used more than elsewhere. In some settings, such as intensive care units, patterns of ordering tests become routine. Where admission procedures entail chemistry tests, physicians may come to expect that information as "simply part of the . . . armamentarium."[27] On the personal level, peers and superiors pressure house staff to do "complete" evaluations and avoid missing a diagnosis. Freeborn and others found that physicians who were high users of laboratory tests tended to be members of clinical groups where the leader was a high user.[28] The social milieu in teaching hospitals probably contributes to greater reliance on laboratory tests there than in community hospitals.[18] Specialist consultants may demonstrate their particular competence by suggesting esoteric tests, although at least one study failed to find a significant relation between test use and board certification.[16] In a small study in Great Britain, Rose and Abel-Smith found that one quarter of general practitioners generated three quarters of laboratory requests.[29] Another British study, using a standardized case presentation, attributed differences in test ordering to differences in experience, background, and training, as well as to other factors.[30]

Defensive and preventive medicine. Fear of malpractice increases a tendency to order additional diagnostic tests, although this effect is probably less prominent for chemistry tests than for other tests, such as radiological procedures. An emphasis on preventive medicine led to the concept of multiphasic screening (the regular, systematic evaluation of apparently healthy patients), and chemistry tests are typically a prominent part of these programs.

Misunderstanding of test results. There has been a great deal of discussion among clinical chemists about problems associated with the term "normal" and the meaning and determination of "normal" values.[31,32] Very often, an abnormal value in a test result leads to additional tests, first to verify the original finding, and second to explain it. An apparently "abnormal" result may be mislabeled for any of numerous reasons, including technical errors, variations in technique, and improperly set normal limits for the patient's age and sex.[33,34,35] Furthermore, as the number of tests given an individual increases, the probability of at least one abnormal result in a completely normal patient also increases, more rapidly than many physicians realize.[36,37,38] For example, if 12 independent tests are administered and each has a normal range defined as 95 percent limits, the odds are nearly even that a completely normal patient will have at lest one abnormal result.* Even a test which is a very powerful discriminator of normal and abnormal will yield a large number of false positives if the prevalence of the target disease is sufficiently low in the test population.[34,39,40] We shall return to this problem in our discussion of the efficacy of chemistry tests.

Evaluation of clinical chemistry tests and laboratories

The desirability of the growth in volume and total costs of clinical chemistries facilitated by technology depends on the benefits the tests confer and the likelihood that more benefits might result from spending the money elsewhere. While a complete answer cannot be given, there appear to be substantial inefficiencies in the clinical laboratory sector, variable quality

*Probability of at least one abnormal result is $1-(.95)^{12}=0.46$. More generally, if each of "n" independent tests has a normal range defined as those results falling within the central "p" percent of results, the probability of at lest one abnormal result in a normal patient is $1-(p/100)^n$.

among laboratories, and unnecessary utilization of chemistry tests. Evidence to support this impression is offered in the following four subsections.

Costs and efficiency

Automation of clinical laboratories over the past two decades has introduced substantial economies of scale, lowering average test costs for high-volume laboratories. The general effect of automation can be represented as in Figure 1, where the three curves represent manual testing, first generation auto-analyzer and second generation auto-analyzer. If a laboratory test volume is less than V_A, its least cost alternative is manual testing. If volume exceeds V_A, but is less than V_B, a first generation auto-analyzer is the best investment, and if volume exceeds V_B, the second generation device is preferred. The farther one goes on the least-cost envelope curve, i.e., the greater the test volume, the lower the average cost per test.

A 1970 survey sponsored by the publication *Laboratory Management* confirms the presumption that large volume laboratories (>100,000 tests per year) should charge less than small volume laboratories.[10] This was true for both hospital and nonhospital laboratories, but small hospital laboratories charged only 6 percent more than large hospital laboratories, while small independents charged more than double the average price of large ones.

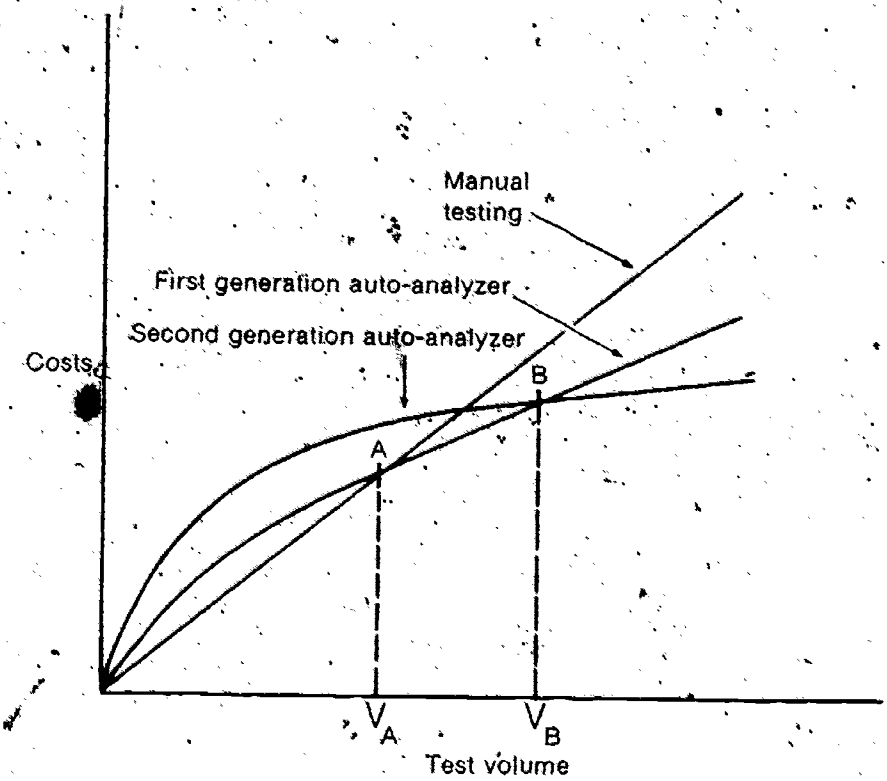
In 1970, average prices for tests in hospitals were 22 percent more than prices for tests in nonhospital laboratories.[10] The Comptroller General compared 1973 laboratory costs for 18 tests in hospital and independent laboratories in three cities and found that hospitals charged an average of 16 percent more than independents.[24] As mentioned earlier, part of the reason for higher hospital charges is their subsidization of other hospital departments. Part may be due also to high fixed costs associated with twenty-four hour service, maintaining a capability to perform seldom used tests, and relatively high pathologist fees. Hospital based pathologists who work on percentage contracts average more than twice the income of salaried pathologists.[21]

Substantial cost savings may be realized by consolidation of hospital laboratories, which in one metropolitan area yielded a 32 percent reduction in average test costs.[2] A 1973 study for the Pennsylvania Department of Welfare projected a potential 55 to 65 percent cost saving if hospital laboratory services were reorganized on a regional basis.[42]

If hospital laboratory charges were revised to eliminate indirect overhead, the cost of laboratory services would be reduced but the overhead would have to be absorbed elsewhere in the hospital. Of course, it is to the hospital administrator's advantage to retain the laboratory financial cushion. It is also to the advantage of the independent laboratory operator, who has a higher hospital ceiling to compare to his own low price. At least one hospital pathologist, noting substantial underutilization of auto-analyzers in several hospitals, proposed that hospital laboratories charge outpatients at competitive rates, thereby raising volume and lowering average costs, just as the independents do.[25]

Figure 1

Effect of automation on chemistry costs



A final layer added to total expenditures for chemistry tests is the excessive mark-up charged by many physicians for tests on Medicare and Medicaid recipients.[26]

Quality

The quality of clinical chemistry tests and laboratories is used here to mean the technical quality of the laboratory result, as measured by such criteria as accuracy (closeness to a standard value), precision (lack of inter-sample variability), and reliability over time (day-to-day reproducibility of results).

Efforts to ensure the technical quality of clinical chemistry laboratories include a voluntary program of inspection and testing by the College of American Pathologists and reviews of hospital laboratories by the Joint Commission on Accreditation of Hospitals. Twenty-six states have laboratory regulations aimed at ensuring technical quality.[1]

In addition, the federal government undertakes a variety of laboratory quality assurance programs. The Food and Drug Administration is empowered to establish product class standards for diagnostic reagents.[43] Under the Clinical Laboratories Improvement Act of 1967, the Center for Disease Control set standards and began testing proficiency of interstate laboratories, but only 900 laboratories have been monitored under this authority.[1] The Bureau of Quality Assurance and the Bureau of Health Insurance have been involved in Medicare certification of laboratories, but this does not entail any proficiency testing. The Clinical Laboratories Improvement Act of 1977 extends the regulatory authority of the Department of Health, Education, and Welfare to additional laboratories and consolidates responsibility for quality assurance in a single agency.

In 1973, the National Bureau of Standards reported a major analysis of clinical laboratory performance that involved more than 1,000 laboratories representing various components of the industry.[44 45] One purpose was to assess the effects of proficiency testing by the Center for Disease Control. While there was some improvement in microbiology performance attributable to proficiency testing, no effect was apparent for clinical chemistries. Some clinical chemists object to automated techniques on the grounds that they may substitute substandard colorimetric methods amenable to automation.[46] In general, the Bureau of Standards found automated methods to be at least as accurate as manual methods and considerably more precise.[44] This finding is consistent with the association between volume of tests and accuracy found in earlier surveys.[47] However, the Bureau of Standards did find results using diagnostic kits to be consistently less precise than other determinations.

While overall accuracy of determination did not improve between 1969 and 1971, there was some decline in variability among clinical chemistry labs, although a considerable amount remained. The principal determinant, appeared to be differences in the particular analytical method used.

Overall, the evidence is reassuring about the technical quality of automated chemistry analysis performed in high volume laboratories. The clinical value of even such accurate and precise information is our next subject.

Effic

Studies of the clinical value of chemistry tests have been conducted in two contexts: first, tests ordered by physicians caring for patients with particular diseases, and second, tests conducted as part of a multiphasic screening program of generally healthy patients or as part of a routine hospital admission battery not explicitly requested by the patient's physician. Studies of the first type were prompted by the suspicion that the rise in use of laboratory services was not being matched by clinical benefits; this impression was generally confirmed. Multiphasic and hospital admission screening have been controversial, and a chemistry battery is usually only one component of these programs. Many careful studies show little if any ultimate patient benefit from chemistry tests which were not solicited by the patient's physician.

As part of their study on the use of laboratory services in a hospital, Griner and Liptzin [14] looked at patients admitted with diabetic ketoacidosis in 1966 and 1969. Patients in the two groups were comparable in age and hospital length of stay, and no stay was terminated by death. Yet the number of laboratory tests increased from 60.3 per patient in 1966 to 76 per patient in 1969. In a later study, Dixon and Laszlo[48] found on average that only 5 percent of hospital laboratory tests altered patient care or helped confirm the existing course of therapy. After instituting a policy limiting each intern to eight tests per patient per day, with each chemical determination defined as a separate test, the authors found that 23 percent of tests altered care. If their study had been extrapolated to the entire hospital, they projected a 25 percent decline in laboratory work load. Although some normal test results influence care, the majority of tests having therapeutic consequences yield abnormal findings. In another approach, Schroeder et al. instituted a laboratory test cost audit and informed each of 33 internists how he or she compared to colleagues in terms of average laboratory costs per patient.[16] In a three-month period following the audit, average laboratory utilization fell 29 percent. In other studies, Schroeder et al. found no relation between physician utilization of laboratory tests and independent measures of clinical competence, productivity, or patient outcome.[49,50]

A few groups have set up objective standards for use of selected laboratory tests and then checked actual use against them. Overuse has been monitored in this way for digoxin level assay[51] and for multiple lactic dehydrogenase (LDH) and calcium determinations.[52] Goldberg and Abbott found that only 19 (70 percent) of 27 digoxin assays ordered during a one-month period satisfied the standards established for ordering them.[51] Results were abnormal in 15 (79 percent) of the 19 tests, but only 2 (25 percent) of the 8 inappropriate tests yielded abnormal results. Interestingly, appropriate physician action followed for only 9 (53 percent) of the 17 patients with abnormal digoxin levels. Eisenberg et al. notified physicians if they had unnecessarily ordered multiple LDH levels, but this audit and feedback failed to improve utilization.[52] More than half the records audited because of multiple LDH requests showed the tests to have been unjustified, and the frequency of inappropriate multiple calcium tests was even greater.

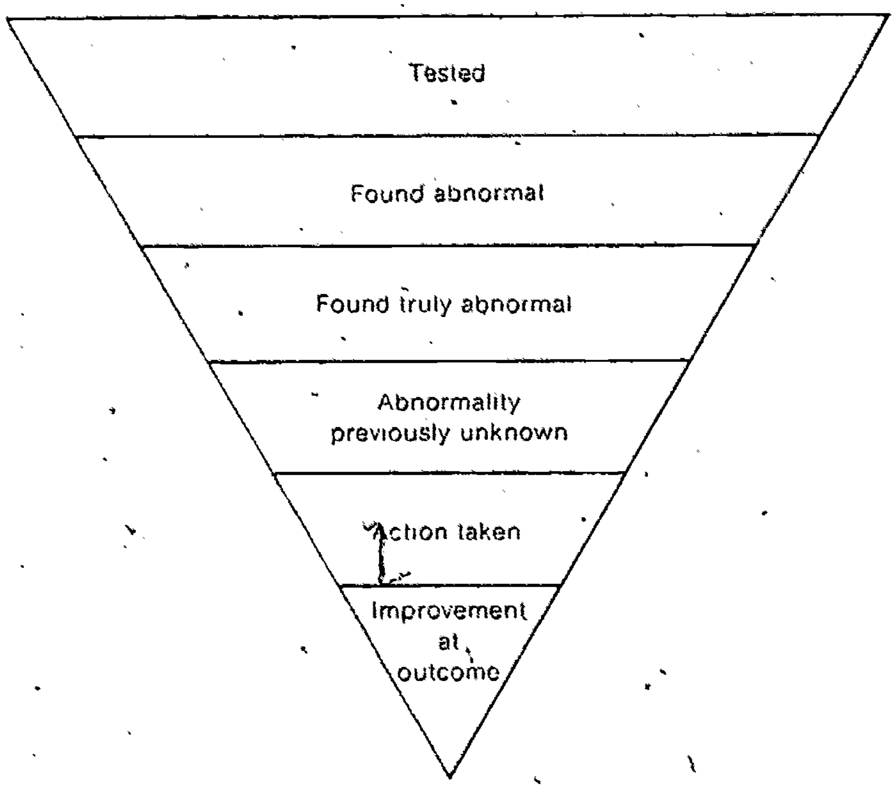
Several controlled studies in British hospitals have examined the effects of unsolicited admission chemistry tests. In one investigation, 1,052 patients were randomly assigned either to an admissions biochemical profile group or to a control group receiving no unsolicited tests.[53] The number of additional chemistry tests ordered in the first week was lower for the group given the admissions biochemical profile, although it is not clear whether the total biochemistry laboratory workload, including the admissions profile, was lower for that group. In this study, unsolicited laboratory tests had little effect on patient care and no effect on the average duration of hospitalization. Another study compared the hospital course and costs for 500 control patients and for an equal number given a biochemistry battery on admission.[54] Various indices of inpatient progress were identical for the two groups, but here the tested group had more additional biochemistry tests and more specialist consultations, and ended up with laboratory bills that were 64 percent higher, and hospital bills 5 percent higher. Beyond unnecessary expense, inappropriate laboratory tests entail inconvenience and potential harm to the patient,[55] although not all laboratory physicians would agree on this point.[56]

Advocates of biochemical screening for ambulatory or hospitalized patients tend to emphasize the number of abnormalities detected[27 57 58] and cost per detected abnormality,[50 60] although some also discuss the significance of detected abnormalities.[61 62] Garfield[63] advocated screening on the grounds that it would increase physician productivity by identifying patients with problems, but others pointed out differences in problems detected by test screening as opposed to physician encounter.[62]

For a screening program to affect patients' health, it must cascade through six levels, represented by the inverted pyramid in Figure 2. Finding a biochemical abnormality on a screening test does not mean that the patient has a truly abnormal chemistry, medical problem, or disease. As mentioned earlier, a reading outside the defined normal range could result from technical error, extraneous factors affecting the test, inappropriateness of norms, or chance variation. Whether an abnormal value represents disease depends on the prevalence of the disease and the distribution of diseased and nondiseased patients across test results. Proper use and interpretation of a diagnostic test depends on the clinical consequences of a false positive or false negative diagnosis and the likelihood of making each mistake, as well as on the underlying disease prevalence.[64] Schoen found no definite medical abnormality in approximately 80 percent of patients initially

Figure 2

Assessment hierarchy for population given a screening test



screened as abnormal.[65] In a five-year follow-up of 200 patients with one or more biochemical abnormalities, Bradwell found that nearly three-quarters either had become normal on retest or had borderline values that were later included in the defined range of normal.[66]

A diagnostic biochemical test cannot contribute to patient well-being unless the detected abnormality was previously unknown. Belliveau reviewed more than 1,000 records for patients given 18 chemistry tests on hospital admission;[67] abnormalities were found in 48 percent of the patients, but more than 70 percent of these were already diagnosed.

If a test result is truly abnormal and warrants further medical attention, physicians still must act on the findings and patients follow proposed treatment, before improvement can result. These steps cannot be taken for granted;[68 69 70] and even if they are taken, the abnormality must be one which is meliorable by treatment.

Perhaps not surprisingly, those who have attempted to relate biochemistry screening to patient outcome have found little effect. Korvin reviewed routine admission biochemistries for 1,000 patients and found no new diagnoses which were unequivocally beneficial to patients.[71] In an ambitious, controlled trial of multiphasic screening, Olson found no differences in ultimate morbidity measures between experimental and control groups.[72]

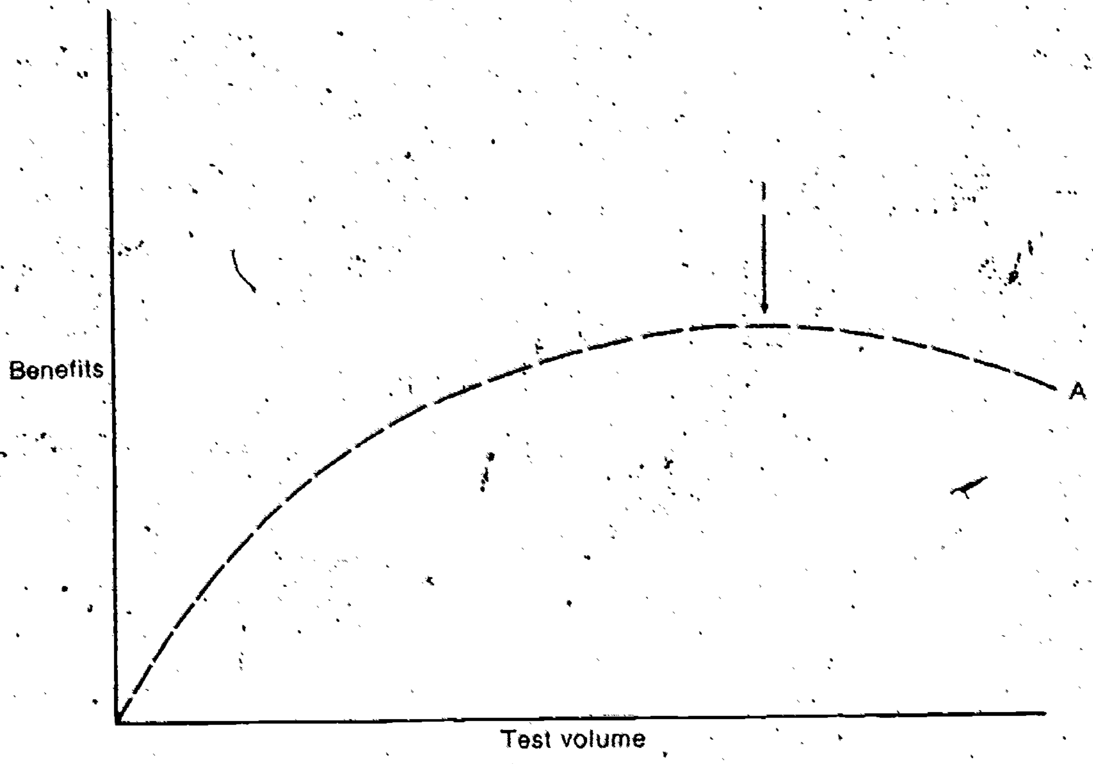
The generally disappointing level of benefits from biochemistry screening should not be taken as contraindicating any test in any apparently healthy or hospitalized population. Specifically, there are arguable benefits from screening for phenylketonuria in the newborn[73] and for lipid disorders, diabetes, and liver disease in an apparently well adult population.[76] But, given the limited evident benefits from both biochemical screening in the general population and unsolicited admission testing in hospitalized patients, the burden of proof for cost-effectiveness of specific tests clearly rests with the advocates of such practices.

Cost-effectiveness

The proper number or chemistry tests is not a straightforward matter, even theoretically, and the following discussion will reveal potential conflicts between optimal decisions for patients individually and for patients collectively or for society. This potential conflict arises from collective responsibility to pay for health care. If we consider only the benefits and risks (i.e., not the resource costs) associated with a chemistry test, we might imagine that the curve for net, total benefits versus test volume would appear as in Figure 3. This curve has an initial positive slope, as patients with the clearest indication are tested first, and then begins to decelerate. The point marked "T" indicates where all patients who stand to benefit have already been tested. Different chemistry tests might be expected to follow a variety of curves of this same general shape (Figure 4). The physician acting in the best interests of the patient, and ignoring resource costs not borne directly

Figure 3

Total net benefits from chemistry test



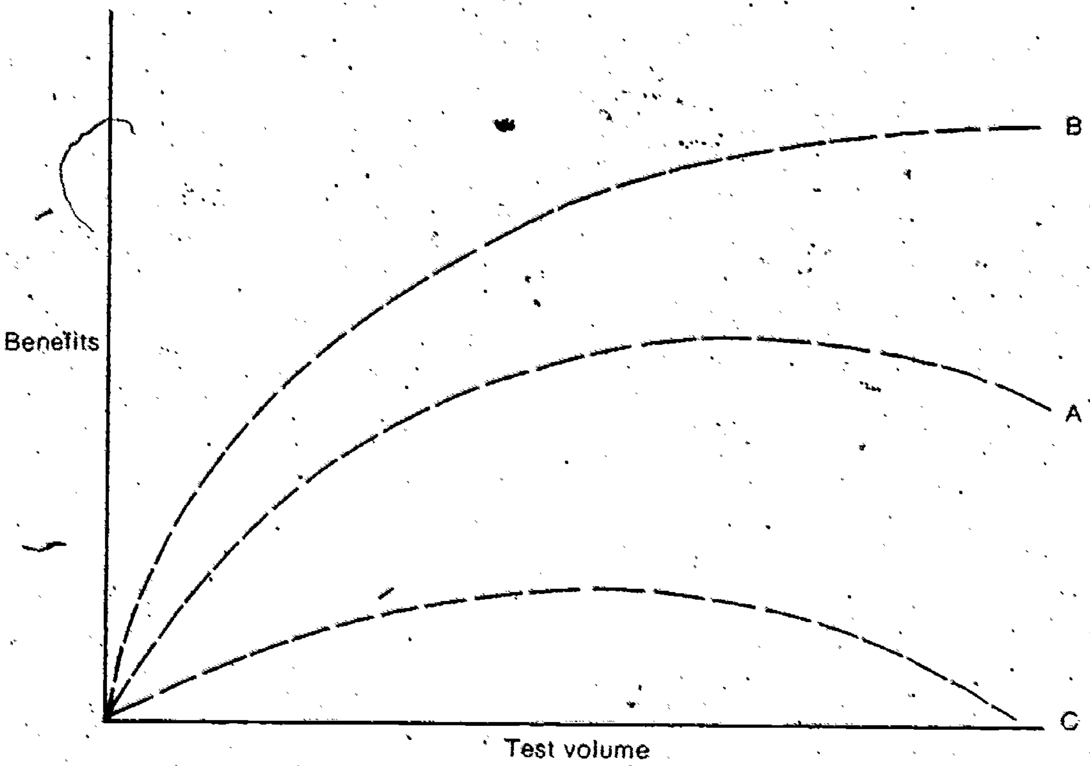
by, the patient, would want to perform each chemistry test up the point where the slope of the benefit curve is horizontal.*

Superimposing the benefits and costs curves illustrates potential conflict between societal and individual decision making (Figure 5). When resource costs must be considered as well as the sum of individual, net benefits, and given limited health resources, the optimal number of tests will depend on the relation of the chemistry benefit curve to the chemistry test cost curve and on the marginal return of other ways of investing the money. In general, the desired level of investment in diagnostic tests from a societal point of view will be less than the desired level from the individual point of view. It is evident from Figure 5 that chemistry test C alone would never be socially desirable, because at any volume its benefits would not outweigh its cost. If a benefit curve persisted at a low but steady rate of climb over a very large test volume, its benefits might outweigh its cost *only* at a high test volume.

*Note, incidentally, that if a physician is limited to using an automated test sequence, this is equivalent to facing an envelope or summation curve of test benefits. Depending on the particular shapes of the component benefit curves, the automated sequence could lead the physician to do more of some tests and fewer of others than would optimally be chosen if the tests were available individually.

Figure 4

Total net benefits from chemistry tests A, B, and C



Conclusions and policy implications

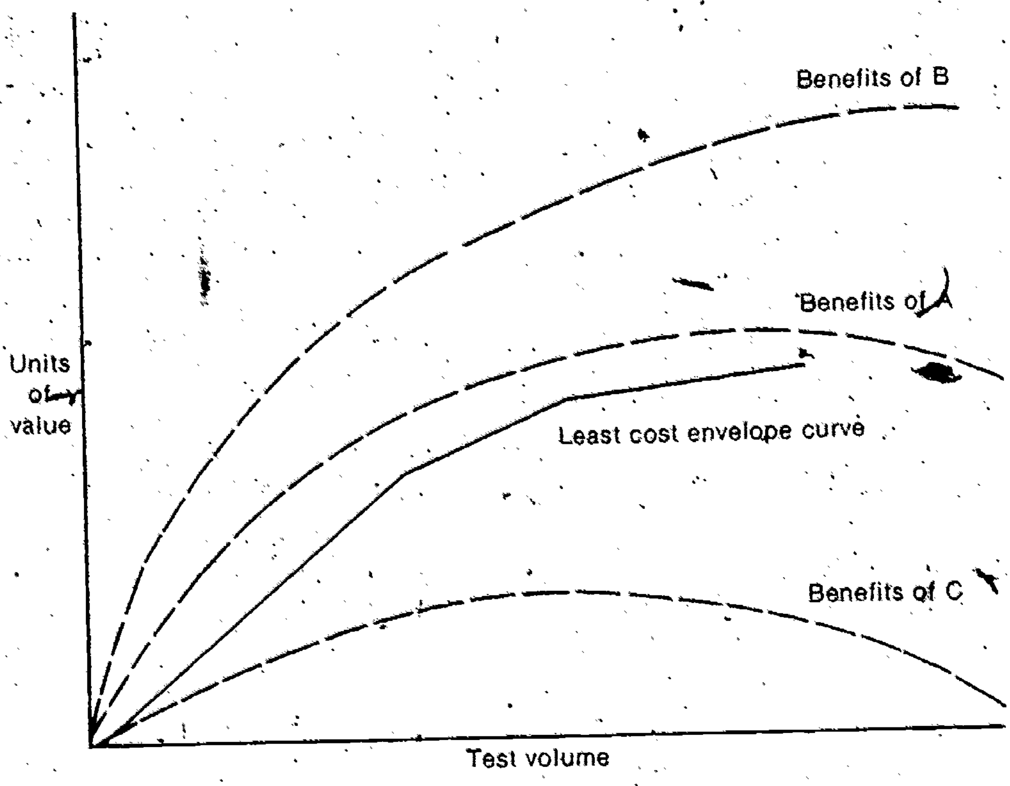
The technology of automation has enabled clinical chemistry laboratories to achieve rapid expansion of services and substantial economies of scale. Although individual test costs are low, diagnostic chemistries account for approximately 2 percent of total health care expenditures. Policy objectives arise in three areas: efficiency and costs, quality, and utilization. Each will be discussed briefly.

Objective 1: Improve production efficiency and reduce overpayment for laboratory services

In practice, this objective means fostering fewer and larger laboratories to do the bulk of inpatient and outpatient chemistry tests through consolidation and regionalization. While high volume means reduced unit costs, it is not clear that either hospital laboratories or independents offer an inherent advantage in terms of resource savings. Each faces some costs the other does not,[25] and higher hospital charges may go entirely to necessary overhead (such as emergency services) and subsidization of other hospital functions. Problems with consolidation and regionalization include institutional pride and individual vested interests, but they can be overcome.[75 76] Kosowsky[1] has proposed a scheme by which cost savings from

Figure 5

Benefits and costs for chemistry tests A, B, and C



eliminating inefficient hospital labs might be shared by hospitals and reimbursers, but true resource savings might be less than reductions in laboratory charges if previously cross-subsidized segments of the hospital still must be supported. Consolidation also offers important advantages other than cost savings.[77]

The clinical laboratory sector has been described both as an emerging oligopoly[19] and as a cottage industry.[2] At present, there does not appear to be much evidence of noncompetitive pricing, and the potential efficiency from fewer, larger laboratories outweighs these risks.

Excess payments by Medicare and Medicaid to private physicians for laboratory services can be most readily eliminated by establishing consistent, fair, fixed-fee schedules.[26]

Objective 2: Maintain and improve quality of laboratory services

The present federal proficiency programs have not measurably affected the quality of clinical chemistry services.[44,45] Fortunately, technology affords both increased efficiency and better quality in the high-volume laboratories.

Since variation in laboratory method and use of certain diagnostic reagent kits are associated with poorer quality performance, regulatory efforts should emphasize control of reagents and methods, areas in which the Food and Drug Administration may exercise considerable influence. The consolidation of federal regulatory programs under the Clinical Laboratories Improvement Act of 1977 should prevent unnecessary duplication of effort by regulators and laboratories.

Objective 3: Promote more appropriate use of chemistry laboratory services

The benefit curves for given chemistry tests (Figure 4) are not known, and, as noted above, there are many incentives prompting physicians to rely on the tests as aids in diagnosis and monitoring. Evidence of substantial reductions in laboratory tests without apparent loss in quality of care suggests that physicians may be operating on the descending portions of many individual patient's benefit curves, or at least on the relatively flat "quality/cost no man's land," where care may appear warranted so long as the physician ignores costs.[78] The fact that reductions in test use could be accomplished at all[16 48] lends some credence to the notion that growth in laboratory use is not inexorable. At present, however, none of the immediate decision makers, physicians caring for patients, clinical chemists, or hospital administrators, has any natural incentive to reduce test ordering.

At least six general strategies might be employed to improve utilization of laboratory tests. Most are aimed directly at the physician ordering diagnostic tests. There have been only a few experiments with these strategies reported in the literature.[16 48 52 79]

1. Education. In so far as inappropriate tests are due to lack of information or misinformation, education programs may improve physician performance. Instruction might cover design of a diagnostic test strategy for different types of patients, appropriate use of particular tests, the meaning of abnormal values and the relation of test results to disease, the distinction between research and clinical use of tests, and the costs of laboratory tests. Such education could be directed at medical students, house officers, and attending staff in classroom settings and conferences and on ward rounds. One aim would be to alter the peer environment that rewards only the most complete diagnostic evaluation and penalizes any oversight. A house staff education effort to improve use of prothrombin time determinations resulted in an initial significant decline in utilization, but a return to previous levels after 18 months.[79] This finding stresses the importance of looking for long term changes in utilization as a consequence of any intervention strategy.

2. Comparison of individual physician test use to group norms. This strategy involves reviewing physician practices to determine the number of costs of tests used for selected types of patient, and telling each doctor how he compares to his peers. An example of this approach was discussed above.[16] Over time, one might expect this practice to exert a moderating influence, tending to move physicians at the high and low ends toward the mean. This might be desirable if, as has been suggested,[49] more competent clinicians tend from the first to cluster about the mean in test utilization.

3. Comparison of individual physician practices to objective standards of appropriate test use. This approach requires a prior determination either of appropriate tests for evaluating certain types of patients or of the range of acceptable uses for a particular test. Unacceptable uses of a test might also be defined and established as a negative standard. Physician use of tests could then be reviewed retrospectively. Where tests are ordered through a computer, it might be possible to institute prospective review and to require explicit physician affirmation before a certain test order could be processed. For example, if a patient's electrolytes had been normal on two consecutive days, a third consecutive order might require affirmation. Such a system might also provide reminders of indicated tests which were not requested. The acceptability of such schemes is unclear, and relatively few hospitals will be equipped with such a system capability in the near future. Schoen proposed that clinical chemists and manufacturers should work toward grouping of subsets of tests which would be more closely tailored to a patient's problems: the required capability is not available in some automated equipment.[65]

In one recent study cited earlier, utilization review against present standards plus notification to physicians of improper testing failed to reduce overutilization.[52] The result raises doubts about the ability of such feedback schemes alone to effect improvements in test utilization.

4. Ration test use. This approach might set a daily limit on the number of tests that could be ordered for a patient, or it might require a physician to maintain no more than a certain percentage of normal test results. An example of this approach was discussed earlier.[48]

5. Alter financial incentives for test use. While clinical pathologist do not initiate tests, those paid on a percentage arrangement have no incentive to discourage increased laboratory utilization. The importance of such an incentive is unclear, and I know of no study testing whether different forms of pathologist reimbursement are associated with different rates of growth in laboratory use. It may be possible to institute some scheme whereby clinical pathologists would gain if laboratory use stabilized or declined. Although ethical issues would need careful consideration, some direct financial incentive to house staff might be attempted in order to reduce inappropriate laboratory use in teaching hospitals.

6. Strengthen laboratory function. Finally, if part of the problem of inappropriate test use relates to laboratory inefficiency or unreliability, some improvement might be expected from strengthening the laboratory function. This might entail internal improvements in management or be accomplished in association with consolidation or regionalization.

A key figure in implementing many of these stragegies is the clinical chemist. Anderson and Benson advocated an expanded role for the clinical pathologist in patient management discussions, medical student and physician education, and development of diagnostic aids and protocols.[80] Like other hospital-based clinical specialists, the clinical pathologist might be contracted to offer "clinical laboratory consultative services." The clinical pathologist would educate house staff and others in the use and interpretation of laboratory tests, establish a test monitoring system, and promote more appropriate utilization of laboratory services. An analogous role has been suggested for hospital radiologists.[81] Such functions for laboratory and diagnostic test specialists would be in the best interests both of patients and of the health care system.

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Assessing the consequences of biomedical research

Frederick C. Robbins

Introduction

The purpose of this paper is to consider the degree to which the consequences of biomedical science have been or can be assessed. Technology transfer or diffusion of technology, although an important and related issue, will not be dealt with as a specific topic. Since the emphasis of this conference is upon the role of technology in the escalation of health care costs, particular attention will be paid to the economic consequences.

Until recently, the research community has given little consideration to the possible economic and social consequences of the application of its findings. Attention has been directed to safety and, to a limited extent, efficacy. With the burgeoning of biomedical science and the increasing complexity of medical technology, along with the realization that resources to support both research and delivery of health services are finite, it is clear that choices must be made in the allocation of research monies. Economic considerations, among others, will be important in influencing these choices.

Thus, there are several reasons why prospective assessment of the outcomes of research might be desirable.[1] First, it could assist in establishing priorities among various projects competing for funds and thus aid in the budgetary process. Second, it could alert policy makers to problems, such as high cost, that if anticipated could be planned for as the technology was introduced into use. Third, it could be valuable in directing the course of the research endeavor.

Not all research can or should be assessed in regard to any outcome other than whether it is likely to add to fundamental knowledge. Research that seeks to do so is usually referred to as basic or fundamental.* The distinction between basic and applied research is not always easy to make, for even the most basic investigation usually has some broad practical goal in mind (e.g., understanding the cause of cancer), and the most targeted or applied research is likely to yield important fundamental information. Nonetheless, it should be possible to identify research that has promise of yielding a result of practical applicability. It is at the time that such a prospect is recognized that assessment becomes a possibility.

The technologies that result from research are of a number of categories, each of which may involve somewhat different types of assessment and regulation. Drugs, biologicals, and more recently medical devices are

*See glossary of terms.

regulated by the Food and Drug Administration, and demonstration of safety and efficacy is required before general use is permitted. No prospective evaluation is required of diagnostic tests or procedures not of surgical operations. Although there are some situations where safety is not at issue, such as a diagnostic chemical test, tests for safety and efficacy could be regarded as essential elements in the experimental protocol for the development of most medical technologies. It will not be possible to discuss safety and efficacy in detail, because the subject is a large one and not entirely germane to the purpose of this presentation. However, aspects that influence the cost of technologies will be touched upon briefly.

Safety and efficacy

Although no one would wish to question the desirability of protecting the public from unsafe and nonefficacious technologies, the economic impact of the regulations controlling safety and efficacy has been both good and bad. The prohibition of unsafe and ineffective technologies from general use results in savings in both dollars and human suffering. Greater cost savings could be achieved by careful scrutiny of the efficacy of much that makes up the present day armamentarium of medicine. Little of what we do has been subjected to rigorous scrutiny, and if it were, much of it would probably not survive. Cochrane has been one of the most vigorous proponents of the need for scientific evaluation of our medical practices and of the savings that could result.[2] A careful examination by an interdisciplinary group at Harvard of the costs, risks, and benefits of surgery has provided interesting insights into the cost effectiveness of such long accepted procedures as tonsillectomy and adenoidectomy, elective hysterectomy, herniorrhaphy, and appendectomy, as well as some developed more recently.[3] Their results challenge many of the ingrained ideas of clinical practice.

Evaluation for safety and efficacy, however, also generates costs, for a variety of reasons. First, administration of the regulations requires a sizable bureaucracy, which must be supported. Second, the tests that are required involve some cost and may delay marketing, both of which can increase the price of the product. It has been stated that the added cost of the tests now required in the development of drugs has had an inhibitory effect upon research in the area and has reduced substantially the flow of new drugs.[4] This effect, of course, can be looked upon as either desirable or detrimental. Clinical trials present the greatest problems as to expense, design, and ethical issues. The randomized clinical trial is the most definitive, and often the only way of determining the value of a medical intervention. In spite of its cost, it is usually, if not always, a saving in the long run both in money and human suffering as compared to the alternative of an inadequate trial, or of trial and error. The issue of its cost benefit is an important one; further data are needed as well as education of both professionals and the public. The ethical problems also deserve more attention, particularly as they relate to children;[5] many drugs are now being prescribed for children without ever having been tested on them, largely because of ethical concerns.

Third, even with the most exhaustive testing it is never possible to rule out all risk or prove conclusively the effectiveness of many technologies until they (i.e., drugs and vaccines) have been in general use for a period of time. An illustration of this problem is the Cutter episode, in which inactivated polio vaccine (Salk type) was found to contain live virus which induced paralytic disease in certain vaccines. This occurred in spite of the fact that the vaccine had been produced under conditions that met all established specifications, and the extensive field trials had revealed no such problem. Thus, it is important where appropriate to provide epidemiologic surveillance for any untoward results after such a technology is in general use. Surveillance should be considered part of the cost of a technology's application. At the present time, the Center for Disease Control maintains surveillance over certain vaccines and procedures, but the effort is not extensive and has never received much support. As a general rule, unfavorable results or reactions are recognized by chance observation (e.g., the thalidomide disaster).

Assessment criteria

In pursuing an assessment beyond the relatively straightforward issues of safety and efficacy, many factors must be taken into account. Not every factor is of equal importance, and a critical aspect of the entire process is the comparative value assigned to each. The process does not lend itself to precise quantitation and involves judgments that reflect the cultural, social, and political environment. In considering this topic I have drawn heavily upon the concept of technology assessment of the Office of Technology Assessment, and particularly the 1976 report entitled *Development of Medical Technology: Opportunity for Assessment*[1] in which the matter is discussed in greater detail. Some of the factors to be considered are:

The economic importance of the disease or condition (often referred to as burden of illness).[6] It should be possible to assess the economic importance of a particular disease or condition with some degree of accuracy. Some of the components that must be taken into account are: (1) the person years of productive life lost; (2) the cost of treating the disease or rehabilitating the victims; (3) the degree of disability, which includes the level of dependency; and (4) the total number of victims. Unfortunately, in practice the necessary data are not always available, and when they are they often lack comparability for different conditions, thereby making difficult the comparisons required for priority setting. An additional factor to be considered is the burden imposed upon family and friends by the care of a sick or handicapped person. This is not something susceptible to quantitation.

The state of knowledge about the disease. Is there adequate knowledge to make the solution of the problem possible or likely? If this can be answered affirmatively, it would be appropriate to proceed with development. If it cannot, support might better be directed toward additional basic research.

Is the research likely to result in measures directed at prevention, early intervention, cure, rehabilitation, or amelioration? It has become fashionable to classify technologies as *definitive* (also *high* or *complete*) or as *half-way*.[7,8,9] A *definitive* technology is one that provides effective control of the disease or condition. As a rule, such technologies result from a thorough understanding of the disease process. Although in some cases recognition of a relatively simple, key fact may be all that is required—Jenner's development of vaccination against smallpox was accomplished before anything was known about viruses or the basic elements of immunity—most present-day problems are not responsive to partial understanding.

When a definitive technology is available, it is usually inexpensive and cost effective. Its cost-effectiveness is enhanced by the fact that it usually supplants less effective and more costly methods. Unfortunately, at the present time there are few definitive technologies. Those that exist usually concern the prevention and cure of infectious diseases. Immunizations are the most dramatic examples; at relatively little cost, a significant number of acute infectious diseases have been almost eliminated or brought under effective control. Cost-benefit analyses indicate highly favorable ratios even when the many intangible benefits, such as parental freedom from worry, are not included.

Antibiotics are another example of definitive technology, even though they are predominantly curative rather than preventive. Ideally, a truly effective treatment should be inexpensive and highly efficacious. It should be possible to diagnose the illness for which it is to be used early enough in its course so that a complete cure is regularly achieved. Penicillin treatment of pneumococcal pneumonia or streptococcal sore throat is an example. Other examples of definitive technologies exist and have been discussed fully by others. However, as they have pointed out, the list is not long.

Most interventions employed fall into the category referred to as *half-way* technologies. These are generally treatments directed at correcting the effects of disease or palliating them. It has been pointed out repeatedly that such measures are less satisfactory and more costly than definitive technologies. One hardly needs to indulge in elaborate cost-benefit analyses to recognize the advantages of poliomyelitis vaccine over respirators, crutches, and braces. Nor do we have to elaborate on the extraordinary costs of kidney dialysis and transplantation or coronary bypass surgery as compared to simple measures, if they ever prove possible, to prevent chronic kidney disease or arteriosclerosis of the coronary arteries. Without belaboring the point, it seems reasonable to conclude that where alternatives exist, resources should be directed so as to encourage the development of definitive technologies as opposed to half-way measures.

What population would be affected? Would a broad segment of the population or only a small group be benefited? The issue is not simply a quantitative one but concerns equity of access to resources as well. In general, priority should be given to technologies that benefit more rather than fewer persons. On the other hand, important considerations of public policy might dictate that a technology that benefited only a small segment of the population nevertheless receive high priority. Disabled veterans might be a population warranting this kind of special consideration.

What is the impact upon the quality of life? Although difficult to define, the effect upon the quality of life needs to be included in the economic and social equation. Any effective procedure or technology improves the quality of life to some extent. An effective preventive or treatment for the common cold, as an example, would have its maximum impact on the quality of life and man-days worked and relatively little on mortality. An important aspect of quality of life is the degree of dependency of a person upon others, because of old age, illness, or disability. Any measure that reduces a person's dependency improves the quality of life for the individual and for those responsible for his care. It also may make a significant saving in dollars.

When is assessment appropriate?

At various stages in the course of work in a particular area it would be possible to assess, using the criteria outlined above, the expected impact, economic and other, of the technology were it to be brought to fruition. The number of uncertainties decreases as the development of the procedure or technology approaches its final stages. However, an assessment can be made at any stage of development, provided the goal is clear and one or more expected outcomes can be defined. Such an analysis may require setting up a number of possible outcomes and assessing each such scenario separately. One value of this approach is that it may permit the selection of the most promising course or courses of action to pursue from among a number of alternatives.

If assessment is to be attempted while the research leading to the development of technologies is still in progress, the earlier this can be done, the better. However, it is obvious that the point the research has reached along that theoretical continuum: from basic research to general application of its product (a fully developed technology), will determine the appropriateness of evaluation and the accuracy of any predictions that are made.

As stated above, basic or exploratory research by its very nature usually is not suitable for assessment. Once a practical outcome such as a device, procedure, drug, or biological becomes a real possibility, the research could be considered as entering the applied area and a preliminary assessment could be conducted. How elaborate the assessment should be will depend upon the importance of the problem, the type of outcome expected, and many other considerations. At this stage, tests in animals for safety and efficacy should be underway or contemplated.

After completion of animal tests and before the first small scale tests in man are begun is the time when a more complete assessment would seem to be most appropriate. If it is deemed wise to stop or decelerate development, it would be best to do so before conducting larger scale field tests and controlled clinical trials, which represent large investments in effort and money.

Past record of assessment

Until now we have been discussing assessment of the consequences of research as if such assessment had not been conducted in the past. In fact, for many years judgments concerning budgetary priorities and the direction of programs have been based upon many of the considerations listed above. Nevertheless, although it is not easy to obtain precise data, the impression is that the National Institutes of Health, the principal source of support for biomedical research, have not conducted evaluations other than for safety and efficacy in a systematic manner. In particular, the economic consequences have received little attention.

When the National Institutes of Health were asked by the Office of Technology Assessment for an enumeration of their activities that might be classified as technology assessment, only three of the institutes reported any such activity, and only that within the National Heart, Lung, and Blood Institute appeared to be concerned with economic consequences. Although this probably does not give a complete picture, it does confirm the impression expressed above.

Nonetheless, it is apparent that the National Institutes of Health have made efforts to evaluate research programs for the purpose of setting priorities and anticipating outcomes, although economic implications have not been a major concern, and the effort has not been clearly focused. Furthermore, neither the National Institutes of Health nor any other body has had a mandate to perform this function. It should be recognized that the Congress plays an important role in priority decisions concerning biomedical research. The budget, as approved by Congress, has built into it mandated programs which specify amounts for each of the individual categorical institutes; this to some extent limits the options available to the National Institutes of Health administration. The congressional review of the budget, which includes hearings and other input from the public, might be considered to fulfill in part the purposes of a technology assessment. Such procedures, however, lack precision and have not employed the specific techniques of assessment. So far, the Office of Technology Assessment of Congress has not been used significantly for this purpose in the health area.

The history of the introduction of dialysis and transplantation for the treatment of kidney disease provides an example of an effort to do an assessment. It illustrates the difficulties of performing assessments and also the fact that such analyses do not always have much influence upon the final policy adopted.

The high cost of the national program for the care of persons with end-stage kidney disease, a program that relies predominantly upon hemodialysis and kidney transplantation, is often used as the ultimate example of half-way technology out of control. It is interesting to note that at least two reports have analyzed the implications of the use of dialysis and transplantation in the care of patients with chronic kidney failure. Although neither was a technology assessment in the strict sense, both attempted to make estimates of the burden of disease, the expected outcome of its treatment, and its cost.[7]

The cost effectiveness of treatment and the overall cost of various alternative national programs were calculated. The reports of both of the studies were issued in 1967. One study was conducted under the supervision of an expert committee chaired by Dr. Carl W. Gottschalk.[8] The report was submitted to the Bureau of the ~~Budget and~~ is commonly referred to as the Gottschalk report. The other was an internal document of the Public Health Service prepared by a group of staff members from the various Bureaus of the Service.[9] This report probably more nearly represents a technology assessment than does the Gottschalk report, since it attempts to analyze alternatives without recommending a specific course of action. By contrast, the Gottschalk report strongly supports the concept of a national program covering all patients with chronic kidney failure.

In retrospect, both studies probably were overly optimistic about the prospects for transplantation. However, the cost predictions of the Public Health Service report were very close to what actual costs have in fact turned out to be; those of the Gottschalk report were very much lower. These two studies illustrate some of the difficulties of doing accurate assessments even in areas where the data are reasonably precise and available. However, they do represent serious efforts to anticipate the implications of technological development.[5] They may have come rather late ~~in the~~ course of the development of dialysis and transplantation, since both were already being applied on a limited scale. However, the Public Health Service study did give a clear warning of the high cost that could be anticipated from a program such as the one that was ultimately adopted. This is a clear illustration of the fact that the rational analysis of a problem does not necessarily determine policy decisions. A detailed analysis of the kidney disease program is to be found in the paper by Rettig in this proceedings.[10]

Future responsibility for assessments

In looking to the future an obvious question is: where should the responsibility for assessing the potential impact of research programs be lodged? In approaching this question the several purposes of assessment should be kept in mind: priority setting, guiding the course of research, and alerting policy makers to opportunities and problems. It should also be recognized that the auspices under which assessment is conducted might differ depending upon the stage of development of the technology. However, no matter where the responsibility is placed, certain general considerations should be taken into account.

1. The assessments should be the responsibility of those familiar with the process of assessment, with participation by persons from a variety of disciplines and interests, including economics.

2. There should be a method for selecting those projects or technologies appropriate for formal assessment. The process of assessment is expensive and could not be applied to all technologies, at least not to its fullest extent.

Thus, judgments will have to be made by competent observers including scientists, administrators, and the investigators.

3. Those responsible for the assessments should not be separated too far from the science base, either geographically or intellectually.

4. Ideally, those responsible for the assessment process would have research interests in technology assessment and would be encouraged to pursue such investigations actively.

5. The process of assessment should be funded separately; it is important that monies for assessment not be taken from existing research resources.

6. The assessment process should not only be coupled closely with the related scientific activities but have free communication with those responsible for policy in the health field, providers of health care, evaluators of safety and efficacy, regulators, and the public.

With these criteria in mind, the National Institutes of Health would seem to be the obvious candidate to be the lead agency responsible for technology assessment. Its mandate is sufficiently broad to permit such a role. Indeed, the National Institutes of Health administration has made significant moves in the last year or so in this field by appointing an Associate Director with responsibilities in the area of assessment and technology transfer.[11]

However, there are several negative aspects to assumption of the role by the National Institutes of Health. It might be argued that engaging in such activities would divert funds and energy from the more important activity of basic research. This is obviously of great concern to a research community that is already feeling the pinch. It is also probably true that the National Institutes of Health have limited expertise in the area. (This disadvantage is hardly peculiar to the National Institutes of Health since there are few persons anywhere with special competence or experience in this field.) Perhaps the most serious reservation about the National Institutes of Health as the agency to do technology assessments would be that, as the funding source for the research underlying most health care technologies, it might have a vested interest in demonstrating a technology's utility, thereby making it difficult for objective evaluation to occur under its sponsorship. The following quotation expresses this point of view: "Studies of technology assessment indicate that assessment is more reliable and instructive when performed by individuals or organizations not directly responsible for the program or policy being assessed."[12] This conflict might be overcome in part by creating a separate institute or autonomous structure within the National Institutes of Health that would have its own staff and budget but would respond to the Director.

Other existing agencies that might assume this role would be the National Center for Health Services Research or the Center for Disease Control. However, each of them, particularly the former, would suffer from a lack of immediate ties to the biomedical scientific community. A new agency or office in the Department of Health, Education, and Welfare could be created for the purpose of technology assessment. Finally, a nongovernmental agency such as the National Academy of Sciences might be assigned this task.

Each of the alternatives has its merits and demerits, and only after careful study should any final decision be made. However, in view of our meager experience in technology assessment in the health field, it would seem prudent to proceed in a modest way with careful evaluation of the results.

Of course, the vital question still remains: If the resources are provided to do more effective assessments of research leading to new technologies, will such assessments materially decrease the introduction of half-way technologies and encourage the development of definitive ones? One can only say that if it is properly done, and if the results are heeded by policy makers, technology assessment could provide a more rational basis for certain priority decisions that might serve to inhibit the development and introduction of technologies with unfavorable cost-benefit ratios. It also could provide an early warning of technologies which, although desirable and cost effective, might present special problems of an economic, ethical, legal, or other nature.

Summary and comment

I fully realize the skepticism with which some regard cost-benefit analyses and I share it to some extent.[13 14] There is danger in placing numbers on pseudoquantitative data, and the results must be interpreted with caution. Nonetheless it does seem that rough estimates can be made which could be useful to those concerned with setting priorities and planning for the allocation of resources.[1 2 3 13 16 17 18 19 20 21] An assessment of the anticipated costs of the introduction of an artificial heart or a new vaccine can, if nothing more, alert those responsible of what costs to expect. In the last analysis, decisions will be made on the basis of broad nonquantifiable issues of a philosophical, moral, social, and political nature. In past experience, even when assessments have been made, political considerations have appeared to dominate, with little attention paid to the results of the assessment. There is reason to believe, however, that with the present concern about costs and limited resources, decision makers are most interested in the results of assessments and are more prepared to give them serious attention. Thus, it becomes important that we learn how to perform assessments well and at minimal cost. It is evident that it is an activity with which we have had limited experience, and in this area, as in science generally, we must be careful not to promise too much nor to allow spurious figures to substitute for common sense.

We need to improve our capacity to assess technologies during the developmental stage and to encourage those projects that have the greatest promise for yielding effective outcomes with high cost-benefit ratios. It is true as stated by Callahan[13] that when one encourages investment in preventive measures one may have to ignore the currently ill. However, it is also true that such difficult decisions may have to be made, and indeed, are now being made, often by default, without the conscious realization that this is what is occurring.

I would add further that what seems to be happening in some quarters is a retreat from the desire to increase our knowledge because we find it difficult to deal with the consequences of what we learn. I would suggest that many of our problems derive from:

• the way in which we reimburse for medical care, which tends to encourage hospitalization and the use of expensive technologies;
• the open-ended nature of Medicare and Medicaid;
• the uncritical way in which new and expensive technologies are embraced by hospitals and other health agencies from motives of profit and prestige;
• the failure of physicians to evaluate what they prescribe either as to its efficacy or as to its cost effectiveness; and
• the inflated expectations of the consumer.

Scientists can make a contribution to the solution of these problems by conducting good research, by assessing the probable outcomes objectively, by communicating their findings in understandable terms, by not over-promising, and by participating in the hard priority decisions along with the other interested parties in our society.

Glossary of terms

Since a number of terms that are used frequently in this paper mean different things to different people, it is necessary to indicate how they are defined for the purposes of this presentation.

Applied research. Research directed to the solution of a practical problem after sufficient basic information has become available. The outcome is more predictable than is that from basic research. Applied research is often conducted on contract, the contractor having specified the product expected.

Basic research. The process of exploring fundamental questions without a precise goal. It may, however, be oriented toward a broad goal (i.e., the cause of cancer, the mechanism of action of drugs, etc.) and is usually focused toward a particular area of research (e.g., genetics, developmental biology, neurobiology, endocrinology). The outcome cannot be anticipated readily but will add to the fund of knowledge about biological phenomena. It is usually initiated by the investigator.

Cost-benefit analysis.[23] Analysis in which all the costs and benefits of a course of action are enumerated, expressed in monetary value, and compared.

Cost-effectiveness analysis.[15] A means of comparing the value of alternative courses of action (costs) which does not, however, reduce all components to monetary values.

Efficacy.[22] Refers to the degree to which a technology produces the desired effect. It is often used synonymously with effectiveness. However, it may also be used to describe the effect under ideal circumstances, while "effectiveness" describes the effect in normal circumstances of use. Cochrane, on the other hand, defines these terms in the opposite way.[2]

*Technology.** Health technology is used here in a broad sense to include the techniques, drugs, biologicals, equipment, and procedures used by health care professionals in providing health care and in operating the systems within which care is provided. Thus a drug, vaccine, or surgical operation would fall within this definition, as would the computerized data system of a hospital or a computed tomography scanner.

Technology assessment. Refers to the systematic analysis of the anticipated impact of a particular technology in regard to its safety and efficacy as well as to its social, political, economic, and ethical consequences.

*Adapted from Office of Technology Assessment Report.[1]

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The dynamics of medical technology use: Analysis and policy options

Steven A. Schroeder, and Jonathan A. Showstack

Introduction

This report surveys the forces within the medical care system that affect the acquisition and use of medical technology and discusses briefly the policy options that are currently being employed, or being considered, to control the spread of medical technologies. We believe that medical technology is neither inherently beneficial nor harmful, neither cost raising nor cost lowering. Discussions of the spread and cost of technology must be based on the premise that we need to utilize better the technologies we have and to promote the use of technologies which are more efficient, both clinically and economically.

Technology here refers to the production of new techniques, procedures, or devices. Organizational structures, medications, and information processing systems have been omitted from the definition. An attempt has been made to be nonjudgmental about medical technologies, although obviously some technologies should be encouraged while others should not. We are primarily interested in the large number of medical procedures, techniques, and devices whose use has been technically validated, but whose appropriate place in medical practice may be unclear.

The emphasis in this paper is on technological procedures and services that are additions to medical practice, and thus cost raising, as opposed to those that substitute for less efficient procedures and services. A macroeconomic view is taken because of the broad national health policy considerations raised by this issue; as big oak trees grow out of little acorns, so do massive national expenditures grow out of individual decisions concerning the use of particular procedures and services. Although many economic issues are discussed, we also consider quality, appropriateness of care, and and ethical issues relating to regualtion of new or existing technologies.

Although the concept of diffusion of medical technologies has been addressed in several reports,[1 2] few empirical studies shed light on the mechanisms by which specific technologies spread throughout the scientific and medical communities. In this paper data and conjectures concerning this process will be presented and the impact that technologies have on the delivery and cost of medical care in the United States will be discussed.

This report is divided into two major sections. The first section discusses the forces within the medical care system that promote the acquisition and use of medical technology. The quality of the data base is questionable.

Gordon and associates report that only eight of 2,000 studies reviewed for a conference on the diffusion of medical technologies related to technology spread in medical organizations; none of these studies were experimental in nature.[2]

The second section of this report discusses policy options for affecting the spread of medical technologies. Some of the facets of each option that may limit or enhance its effectiveness will be described.

Almost all the factors in the medical care sector promote the acquisition and use of medical technologies. As currently structured, individual policy options have only a limited effect on this issue. It is our conclusion that the problems associated with the appropriate spread and use of medical technologies are so complex that they require a unified, systems approach, which would allow innovation and diversity while recognizing our limited financial resources.

The medical care system

Forces exist within our medical care system that encourage the rapid spread and use of medical technology. These include concerns for high quality and efficient care, as well as financial gain and competition. The educational system in which physicians are trained, the structure of the reimbursement system which physicians and hospitals are paid, and consumer demand encourage the relative uncritical use of medical technologies. The following is a discussion of the key factors within the medical sector that impact most directly on the acquisition and use of medical technologies.

The physician

The fee-for-service reimbursement system contains large incentives favoring technology-intensive medical practice. As the fee-for-service reimbursement system has developed in this country, particularly over the last 25 years with the undertaking of relative value studies (RVS), the price structure has been increasingly formalized. This system includes incentives to the individual physician to order ancillary, often technological, services. Not only are RVS schedules used in many states for physician billing, but several studies have used RVS coding and/or unit valuation as approximations of the true economic value of services.[3 4 5]

Relative value studies attempt to assign relative values to procedures and services. These values, theoretically, correspond to their true cost. The "value" assigned is basically economic; it does not include questions of clinical or social worth. If one procedure, such as a tonsillectomy, is given an arbitrary value of one and another procedure costs twice as much as a tonsillectomy, then this second procedure should be given a relative value of two. An RVS schedule is not necessarily a fee schedule, but can become one through use of appropriate conversion factors. For instance, if a tonsillectomy is worth one unit and if the conversion factor is $100 per unit, then a tonsillectomy would justify a $100 fee and a two-unit procedure would justify a $200 fee. An RVS not only creates set value relationships but also tends to rigidify the pattern of delivery of medical services. It also provides incentives to perform overvalued (high charges in relations to cost) services.

The California Relative Value Studies (CVRS),[6] which is issued by the California Medical Association (CMA), is segmented into specialty areas, on the theory that different rates of overhead and technological innovation in the four major sections of the CRVS (Medicine, Surgery, Radiology, and Pathology) create a need for different conversion factors to be applied to each section. It was felt that technological services such as radiology and laboratory have a greater chance for movement toward more productivity and efficiency over time.

Relative values were originally established by surveying a random sample of CMA physician members, who were asked to list what their charges were for approximately 700 procedures and services. More recently, automated data processing has allowed the establishment of relative values as the relationship between the median charges for services billed through Blue Shield of California. All relative values must be approved by various specialty committees within the CMA.

The RVS system is used by Blue Shield of California as it administers its usual, customary, and reasonable system of payment. The highest allowable reimbursement for a service, or payment screen, is based in part on the value assigned to that service by the CRVS. Since the payment grid is based on the relative value for a service, which in turn is based on charges, there is a built-in inflationary bias. As long as charges are allowed to rise the payment grid will eventually increase.

What happens if a claim is received by a third-party payer for a service that has no charge or payment history? Blue Shield of California sends the claim to a physician who is a specialist in the field of that particular service; a value is set based on the physician's knowledge of that service. After enough claims for a particular service have been received, a firm value is established. Charges may not be the only basis for establishing this value, but they are, in fact, dominant. While this process devotes considerable energy to establishing a relative value for a service, it does not question its appropriateness or effectiveness.

When technologically innovative medical services come onto the market, high charges are often made to recoup research and development costs, as may be the case with many laboratory tests, or to pay for the initial training to perform or interpret the result of the procedure, such as the charge for reading a computed tomographic (CT) scan. The charge may be set even higher because of a low estimate of yearly volume. Whatever the reason, the structure of the reimbursement system makes it very difficult to lower charges once they are set at a high level. The free market forces of competition simply do not operate in the medical care field toward lowering the charges for most services rendered.

The following theoretical example (excerpted from a paper written by the authors[7]) demonstrates, by examining a set of model medical practices, that the existing fee and pricing system provides financial incentives for the use of technology-intensive medical care even within the primary care field of general internal medicine. These incentives result from the high financial reward given to technological services as opposed to consultative services. For instance, a periodic physical exam that takes about 45 minutes of the physician's time carries a charge of approximately $40. On the other hand, administering and reading the results of a chest x-ray or of an electrocardiogram (EKG), both of which take no more than a few minutes of a physician's time, carry fees of approximately $28 each. Without arguing the clinical efficacy of these tests, it is clearly in the physician's financial interest to order technological procedures.

In this example, four theoretical models of office practice (Models A, B, C, and D) are constructed. All models assume that the specialty of the physician is internal medicine and that the "patient mix" (distribution of visits between history and physical examination visits and general return office visits) is constant. Models A, B, and C assume that the physician is in solo practice. Because of larger capital investment required for equipment, Model D assumes a four-physician general internal medicine group practice. No procedures or tests are performed in the physician's office in Model A. Five basic procedures and tests are performed in Models B and C: electrocardiogram, urinalysis, complete blood count (CBC), sigmoidoscopy, and tuberculin (TB) skin test. The basic differences between Models B and C are the percentages of patients receiving each type of ancillary service, generally with more patients in Model C receiving ancillary services than in Model B (Table 1). Three additional diagnostic procedures are performed in Model D: a two-view chest X-ray, a treadmill cardiovascular stress test, and an automated 12-channel blood chemistry test. A Model D physician is also assumed to perform the first five procedures and test to the same degree as a physician would in Model C. Slightly fewer than one-quarter of all office visits are history and physical examinations, while the remainder are general return visits. These visits and various procedures and tests are listed in Table 2, along with the way charges were derived.

Income statements for each model are shown in Table 3. (For a more detailed description of the assumptions underlying this analysis, see

Table 1
Percentage of patients undergoing in-office procedures and tests according to practice model

	Model A		*Model B*		*Model C*		*Model D*	
Procedure or test	*H & P* [a]	*General* [b]	*H & P*	*General*	*H & P*	*General*	*H & P*	*General*
EKG	0%	0%	40%	7%	75%	10%	75%	10%
Urinalysis	0	0	100	20	100	30	100	30
CBC	0	0	100	15	100	20	100	20
Sigmoidoscopy	0	0	25	3	50	5	50	5
TB skin test	0	0	90	3	90	5	90	5
2-view chest x-ray	0	0	0	0	0	0	75	10
Stress test	0	0	0	0	0	0	20	1
SMA-12 [c]	0	0	0	0	0	0	75	10

[a] H & P = History and physical (22% of all office visits)
[b] General = General return visit (78% of all office visits)
[c] A 12-channel blood chemistry test

Table 2
Revenue and fee assumptions

1. 46-week work year; 30 hours per week for patient office visits.
2. 45 minutes per History and Physical (H & P) examination; 20 minutes per General (return) visit.
3. 700 H & P and 2,500 General visits per year for Model A.
4. Models B, C and D have a reduction (5%, 10%, 15% respectively) in total patient volume due to performance and interpretation of procedures and tests.
5. Distribution of office visits according to 1974 California Relative Value Studies (CRVS) code and unit value, and California Division of Industrial Accidents (CDIA) 1976 conversion factor:

Type	*Description*	*1974 CRVS code*	*Charge per visit*	*Percent of visits (all models)*	*Number of visits (Model A)*
H & P	Comprehensive	90020	$61.25	4%	140
	Periodic	90088	38.50	18	560
	Brief	90040	12.25	8	250
General	Limited	90050	18.20	47	1,500
	Intermediate	90060	22.75	23	750
			Total . . .	100%	3,200

6. Charges for tests and procedures according to 1974 CRVS unit value and CDIA 1976 conversion factors:

Description	*1974 CRVS code*	*Charge*
EKG	93000	$28.00
Urinalysis	81000	3.90
CBC	85022	6.50
Single venipuncture	99018	5.20
Sigmoidoscopy.	40240	32.00
TB skin test	86580	6.50
2 view chest x-ray	71020	26.60
Stress test	93015	105.00
SMA-12	80112	16.90

Schroeder and Showstack.[7]) Net income for Model A, in which no procedures or tests are done in-office, is $31,500. When in-office procedures and tests are performed, and at a progressively higher level of intensity (even with a moderate *decrease* in patient volume), net income rises sharply. Model D, in fact, has a per-physician income almost three times that of Model A ($31,500 versus $90,000). National policy implications are illustrated by the fact that the theoretical cost difference for the over 600 million yearly office visits in this country between the low technology-intensive Model V and high technology-intensive Model D, exceeds $6.5 billion. (This figure is based on a distribution of all office visits similar to that billed through California Blue Shield, that is, approximately 95 percent general (return) visits, and 5 percent comprehensive or periodic history and physical exams.)

These gross charges and net incomes demonstrate the strong economic incentives existing in routine office practice toward use of medical procedures and laboratory tests. These incentives have been acknowledged by such

Table 3
Office income summaries for practice models A-D
(in dollars)

Model A	
Gross charges	$77,560
Costs:	
1. Noncollectables @ 10%	7,756
2. "Other" expenses, including liability insurance, @ 20% of gross charges	15,512
3. Variable expenses	22,800
Net	$31,492
Model B	
Gross charges	114,134
Costs:	
1. Noncollectables @ 10%	11,413
2. "Other" expenses, same figure as Model A, plus $500	16,012
3. Variable expenses	31,955
Net	$54,754
Model C	
Gross charges	125,157
Costs:	
1. Noncollectables @ 10%	12,516
2. "Other" expenses, same figure as Model A, plus $1,000	16,512
3. Variable expenses	36,126
Net	$60,003
Model D (4-physician group)	
Gross charges (161,586 per physician)	646,344
Costs:	
1. Noncollectables @ 10%	64,634
2. "Other" expenses same figure as Model A, plus $1,500 (×4)	68,048
3. Variable expenses	154,815
Net	$358,847
	= $89,712 per physician

academic internal medicine spokespeople as Petersdorf[8] and Seldin.[9] Data reported by Childs and Hunter also support the hypothesis that these incentives affect the way a physician practices. They found that non-radiologists who provide direct X-ray services use diagnostic X-rays more frequently than do those who refer patients to radiologists.[10]

Even with a lack of evidence about the efficacy of performing periodic testing,[11 12 13 14 15 16 17] physicians continue to prescribe and administer, often with great differences in frequency, many of the procedures used in this theoretical example.[18 19 20] Under our current reimbursement mechanism, no constraints limit the ordering of these procedures. While it can be argued that a physician is medically justified in ordering many of them, and that many patients expect these procedures to be part of a routine office visit, we question whether the reimbursement system should provide the demonstrated financial incentive to do so.

Table 4

Certificates granted to internists by the American Board of Internal Medicine, 1965–1976 [a]

Year	Number of certificates granted: General	Specialty	Total	Percentage specialty certificates
1965	1,345	79	1,424	5.5%
1970	3,132	200	3,332	6.0
1972 [b]	3,337	1,805	5,142	35.1
1973 [b]	3,097	1,183	4,280	27.6
1974 [b]	2,898	2,383 [c]	5,281	45.1
1975 [b]	3,262	2,381 [c]	5,643	42.2
1976 [b]	3,971	1,484 [c]	5,455	27.2

[a] Personal communication, George D. Webster, M.D.

[b] Certificates for nuclear medicine include internists only. Personal communication, John Ross, M.D.

[c] Allergy and immunology certificates reduced by 40% to correct for pediatricians. Personal communication, John Salvaggio, M.D.

Increased specialization, identification of specialty with procedures, and physician surplus. It has become almost a cliche that physicians are the most important determinant in the allocation of medical care resources. The increased tendency toward subspecialization and the increase in numbers of physicians per population are two recent trends that have important implications for the use of medical technology.

Robert Chase, former president of the National Board of Medical Examiners, has summarized what he calls the "disturbing cycle" of specialty certification:[21]

1. As a result of advances in a field or development of *new technology* [emphasis ours] a new group develops a special expertise in this area.
2. An organization or society is formed for an exchange of ideas and to display advances to one another.
3. Membership in the organization becomes a mark of distinction in the field, and, in an effort to externalize that recognition, certification of excellence in the field becomes established.
4. Institutions with responsibility for quality of health care soon accept certification as evidence of competence and limit care within that field to those certified.

Chase notes that in 1976 the American Board of Medical Specialties listed 22 medical specialty boards that confer general and special certificates in 65 areas of medical practice. He predicts that an additional 20 areas of special competence are likely to qualify for certification within the next several years.

Petersdorf, in a 1976 editorial in the *Annals of Internal Medicine*, criticizes the trends toward excessive subspecialization and the progressively greater use of new technologies. He links subspecialization with increased physician costs as well as with increased hospital costs and deplores the excess of subspecialists as compared to general internists.[22]

Data from the American Board of Internal Medicine show increased issuance of subspecialty certification in internal medicine. In 1972 the Board expanded its number of subspecialty exams from four to eleven. This change was followed by a prompt increase in the percentage of candidates who went on to obtain subspecialty certification (Table 4). The year-to-year variations reflect various factors, including the fact that most of the subspecialty boards examine only every other year. Of particular interest are the data from 1975, when 1,052 cardiology certificates were granted, accounting for 19 percent of all certificates granted that year.

Medical specialty fields have become prominently linked with new developments in medical technology. It is unclear to what extent this linkage has been promoted by the bias in the fee structure described earlier, but, the very least, reimbursement affects the rate of technology diffusion. Indeed, it can be claimed that overutilization of expensive diagnostic procedures has become the internist's version of excessive surgery.

For example, in gastroenterology the recent development of flexible fiberoptic endoscopy using a "cold" light source has led to an explosive increase in the incidence of and indications for upper gastrointestinal endoscopy. This procedure now merits its own society, the American Society of Gastrointestinal Endoscopy, and its own journal, *Gastrointestinal Endoscopy*. Though gastroscopy normally takes less than 30 minutes to perform by an experienced endoscopist, typical reimbursement for a procedure of this type is approximately $200. Concern over the rapidly escalating indications and apparent increased incidence of upper gastrointestinal endoscopy has led the American Gastroenterological Association's patient care committee to convene a subcommittee to identify clear, well documented indications for performance of this procedure.

The presidential address of the 1976 American Gastroenterological Association focused on the issue of invasive procedures. In this address, Dr. Fred Kern stated that performance of procedures has become the major activity for gastroenterologists. He cites an informal study he conducted among gastroenterological specialists in Denver that showed that 60 to 65 percent of all procedures performed were upper gastrointestinal endoscopies. Kern goes on to say:

> Our enthusiastic and often uncritical acceptance of endoscopic procedures and the nearly open-ended list of indications for their use are troublesome . . . . The three major issues for us are (1) Have endoscopic procedures increased our understanding of disease? (2) Have they improved our management of patients? (3) Are they always necessary and in the best interests of our patients? In general, they have not increased our understanding of disease. The answers to the other two questions are not known . . . .[23]

He questions the wisdom of a system that reimburses procedures far more lucratively than it does a careful history, physical exam, and diagnostic/therapeutic formulation requiring "far more training and experience and much more extensive knowledge and understanding." He wonders whether decreasing endoscopy fees would lower the number of procedures performed.

Gastroenterology is not the only clinical field to have experienced an explosion of diagnostic techniques. Cardiology has witnesses a dramatic increase in the types and refinements of both invasive (cardiac catheterization) and noninvasive techniques (echocardiography, exercise stress testing, ambulatory monitoring of cardiac rhythms, radionuclide imaging, sequential monitoring of electrocardiogram, phonocardiogram, and carotid arterial pulse tracing to determine systolic time intervals). These developments have warranted a spate of recent reviews in the early 1977 issues of the *New England Journal of Medicine*.[24 25 26 27 28 29 30] Similar developments have occurred in other medical fields; for example, the use of fetal monitoring during labor, the burgeoning of intensive care units for newborns, and the almost revolutionary development of new diagnostic techniques in radiology, such as ultrasound, imaging with radioisotopes, and selective catheterization of blood vessels.

Another important factor favoring identification of medical specialties with specific technologies is the impending national aggregate physician surplus, as acknowledged implicitly in the National Health Professions Educational Assistance Act of 1976 (P.L. 94-484), and explicitly by Uwe Reinhardt in his book, *Physician Productivity and the Demand for Health Manpower*.[31] Reinhardt notes that differential hourly income accruing to medical specialists combines with physician-determined demand for medical care to lead to targeting of income independent of local physician density. Thus, given perceived desired income levels and existing reimbursement values for medical care, the use of medical technology will vary directly with density of physicians. While details regarding the concentration of physicians in this country may be found elsewhere,[31 32] it is clear that the issue is one bound closely to medical technologies and cost and must be considered as part of the problem of medical cost containment.

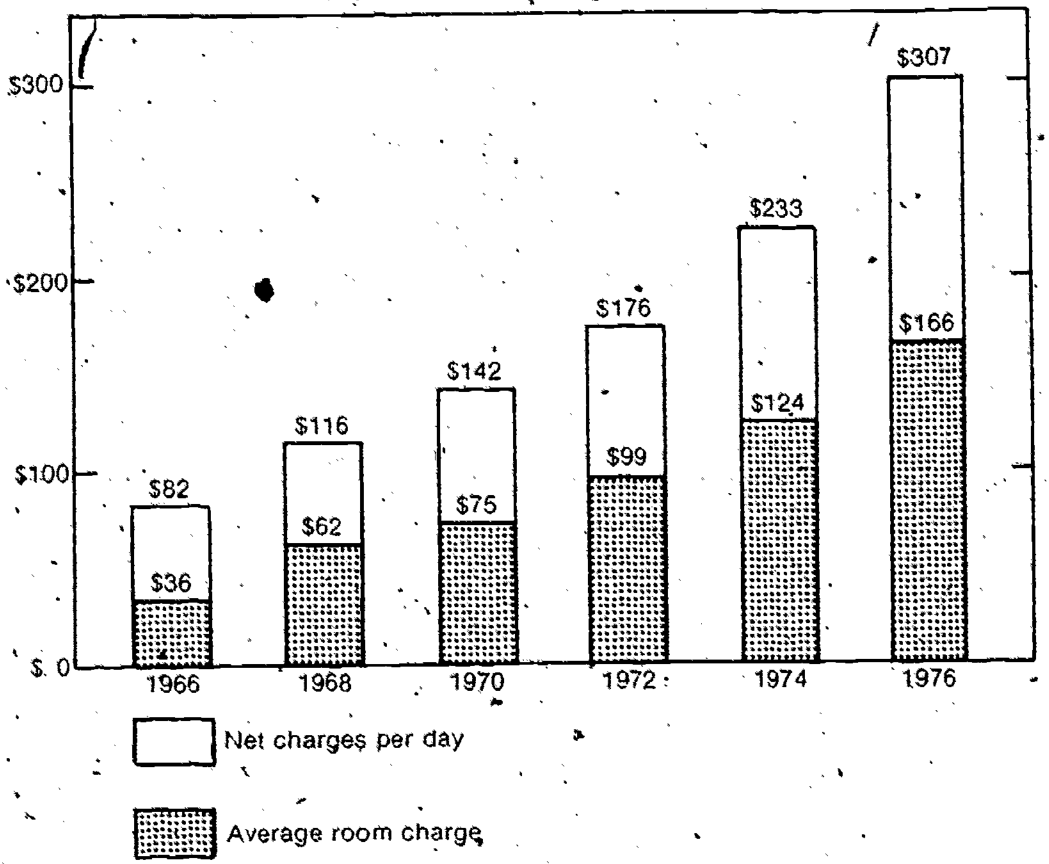
In summary, medical specialties are increasingly linked with new technologies for diagnosis and treatment; the spread of these technologies is explosive; current reimbursement values favor use of technologies, and technology evaluation lags considerably behind its spread into medical practice. The implications for control of technology are serious indeed: Controls will have to contend not only with the reimbursement system as it now operates, but also with the powerful forces toward medical specialization.

The hospital

The hospital is the single most important site for the placement and use of medical technology. Not only is hospital care the most costly sector of American health care, accounting for 39 percent of the national health dollar,[33] but it is also the most rapidly expanding segment of medical care costs. For example, in 1975, approximately $46.6 billion was spent on hospital care, an increase of 16.6 percent over 1974.[33] At one particular hospital, the University of California, San Francisco, room charges and net per diem charges increased approximately fourfold during the period 1966–1976 (Figure 1). Feldstein and Taylor found that 75 percent of the national increase in hospital per diem costs was due to increased amounts of services (as opposed to price increases), a large part of which is probably due to new technology and attendant labor requirements.[34]

Figure 1

University of California, San Francisco, hospital inpatient charges selected fiscal years



Source Data obtained by authors from UCSF hospital financial services

New technologies are distributed widely throughout all areas of the hospital. They include, for example, intensive care units, inhalation therapy, diagnostic radioisotope facilities, radiotherapy, open-heart surgery, and burn units.[35] These individual items may appear to be only a small part of the total Hospital budget; in the aggregate, however, their contribution to hospital costs is large. For example, the budget for inhalation therapy at the University of California, San Francisco hospital in fiscal year 1975–76 was $762,000, accounting for 1.4 percent of the total direct hospital expenses, up from 1.0 percent four years earlier.

Special care units, tests, and surgical procedures. Perhaps the most dramatic example of the institutionalization of new technologies is the special care unit. Despite general acceptance of coronary care units, considerable controversy exists over their effectiveness and cost-benefit.[36 37 38] Martin and colleagues compared changing patterns of inputs into the care of patients hospitalized with myocardial infarction before and after the popularization of coronary care units. They found a dramatic increase in the frequency of chemical laboratory tests, X-rays, and bacterial examinations and lesser increases in electrocardiograms, sedation, and days of oxygen therapy. Despite this more aggressive treatment these investigators found no significant changes in the duration of hospitalization or in hospital mortality.[39]

Griner has made similar observations about the intensive care unit (ICU).[40] He compared the experience of adult patients admitted to Strong Memorial Hospital in Rochester, New York, with the same diagnosis, acute pulmonary edema, both before and after the opening of an ICU at the hospital. Mortality rates were identical for the two groups, but there was an increase in the length of hospital stay (2.3 days) and a 46 percent increase in hospital bills for those admitted the year after the ICU opened. More than five times as many arterial blood gas measurements were performed as in patients admitted before it opened. Almost 90 percent of these measurements were done in patients admitted to the ICU.

Several commentators have pointed to diagnostic laboratory and radiologic procedures as accounting for an increasingly large part of the hospital bill. For example, Griner and Liptzin[41] found that 25 percent of charges at the Strong Memorial Hospital were attributable to diagnostic procedures. They found that over a five-year period, charges for laboratory tests increased sixfold, as compared to a twofold increase in total hospital charges during the same period. They also documented frequent specific patterns of laboratory overuse and redundancy. Similarly, Dixon and Laszlo,[42] at the Durham, North Carolina, Veterans' Administration Hospital, showed that only 5 percent of laboratory data are actually used in diagnosis and treatment of patients. Scitovsky and McCall[43] found large increases in numbers of tests or procedures done for diagnoses of acute appendicitis, maternity care, breast cancer, and acute myocardial infarction between 1964 and 1971 for patients at the Palo Alto Medical Clinic.

A large amount of resources may be used on a relatively small number of patients. A summary of outcomes for 226 patients admitted to the recovery room-acute care unit of the Massachusetts General Hospital in fiscal year 1972–73 shows that after one month, 123 patients had died, 70 were still hospitalized, and 21 were recovering at home; only one of 103 survivors had fully recovered. Altogether, 27 of 62 ultimate survivors fully recovered. Hospitalization charges averaged over $14,000 per patient (in 1972–73 dollars).[44]

The ability of modern technologies to prolong survival in severely ill patients has been vividly documented in the Karen Quinlan case. In many instances it is possible to prolong life for a virtually indefinite period. There are few cases in which some hope of at least partial recovery is not present, and faced with the ethical dilemma of how far to go, most physicians would rather err on the side of excessive rather than insufficient vigor. Although there is evidence of public concern, as shown by the recent enactment of the "right to die" bill in California, and its introduction in other states, it is not uncommon to find examples of hospitals (as we did at the University of California, San Francisco) that are "spending about as much annually in providing essential services to our end-stage renal disease patients as we are for ambulatory care efforts for all our patients."[45] Further, there appears to be powerful national sentiment for passing a version of national health insurance to pay only for catastrophically expensive cases. This form of coverage would only intensify the trends toward prolonging life and increasing medical costs because of the relatively unlimited nature of the funding for chronic disorders that would result. At the University of California, San Francisco Hospital* during the fiscal year 1975–76, 17 percent of patients admitted one or more times had hospital charges in excess of $5,000. These same patients, many of whom had severe chronic diseases, accounted for fully 58 percent of the total hospital charges for that year. It seems clear that so-called "catastrophic" national health insurance will stimulate spending in the area of chronic illness, particularly in fields utilizing what Thomas has called "half-way" technologies,[46] such as renal dialysis, coronary bypass surgery, and total hip replacement.

Childbirth data that we have collected at the University of California, San Francisco Hospital illustrate the change over time toward more highly technological surgical procedures and approaches. Others have noted a direct relationship between increased fetal monitoring and cesarean section deliveries. While the data in Table 5 do not necessarily imply a causal relationship, it is striking that the ratio of cesarean sections to newborns almost tripled between 1965 and 1974.

Other data show the increase in new or technologically oriented operations (Table 6). Not only did cardiac catheterization jump from fifth in 1965 to first in 1976, but only two of the ten most frequent surgical procedures in 1975, diagnostic dilatation and curettage (D & C) and cardiac catheterization, were even listed among the ten most frequent surgical procedures performed in 1965.

Hospital characteristics promoting technology diffusion. What is it about the acute care hospital that promotes the spread of medical technologies, even in the absence of convincing data regarding effectiveness or efficiency? Although a number of financial and structural characteristics such as the cost-plus nature of third party reimbursement and the threat of malpractice

*University of California, San Francisco Hospital is a tertiary care facility. We do not wish to imply that community hospitals have the same experience.

Table 5

Discharges, newborns, and Cesarean sections at University of California, San Francisco, for selected years

	1965[a]	1970[a]	1975[a]
1. Discharges	19,036	19,426	21,146
2. Newborns	2,103	1,812	1,631
3. Cesarean sections	125	161	278
4. Cesarean sections as a percentage of newborns	6%	9%	17%

[a] 1965, 1970 Calendar years, 1975 Fiscal year

Table 6
Ten most frequent surgical procedures for selected years
University of California, San Francisco
(type and number)

Order of incidence	*1965* [a]	*Order of incidence*	*1970* [a]	*Order of incidence*	*1975* [a]
1. Lumbar puncture	731	1. Cardiac catheterization	571	1. Cardiac catheterization	482
2. Bone marrow aspirate	590	2. Bone marrow aspirate	441	2. Cesarean section	278
3. Stapedectomy	420	3. Total-hip replacement	241	3. Total-hip replacement	234
4. Diagnostic D & C	402	4. Stapedectomy	216	4. Endarterectomy	156
5. Cardiac catheterization	306	5. Diagnostic D & C	212	5. Other joint repair & replacement (excluding hip)	151
6. Excision of skin lesion	252	6. Liver biopsy	198	6. Diagnostic D & C	148
7. Lens extraction (intracapsular cataract)	195	7. Thoracentesis	181	7. Intra-amniotic injection to terminate pregnancy	141
8. Liver biopsy	181	8. Skin biopsy	175	8. Kidney transplant	137
9. Excision of lymph node	179	9. Catheterization of "other" intra-abdominal vessels	172	9. Ligation and division of fallopian tubes	130
10. Peripheral blood vessels	158	10. Rhinoplasty	170	10. Repair of inguinal hernia	130

[a] 1965, 1970: Calendar years; 1975: Fiscal year.

Source: Data obtained by authors from UCSF Hospital department of medical records research.

suits are important, we would like to emphasize two specific characteristics of the acute care hospital: the use of technology acquisition to attract and retain physicians, and the unceasing pressure for new treatments and technologies in the face of severely ill patients.

Estimates of an excess of 100,000 hospital beds in this country by 1980 have recently been cited by a committee of the Institute of Medicine.[48] Given this surplus and the increasing pressures for shortening hospital stay through such mechansims as utilization review, Professional Standards Review Organization criteria, and preadmission certification, many hospitals, particularly those in urban metropolitan areas, are hard pressed to maintain their desired occupancy levels. For example, the average length of stay for California acute care hospitals declined from 7.6 days to 6.6 days between 1957 and 1975. During that same period, occupancy rates in California declined from 75 percent to 66 percent. Nationally the number of hospital beds per thousand population increased from 3.47 in 1957 to 4.45 in 1975.[49] Since most hospital costs are relatively fixed, the impact of lowered occupancy is to raise per-patient costs. The hospital must cover these costs, not only through increasing charges for per diem and/or ancillary services, but also by attracting patients (through their physicians). Hospitals, therefore, find themselves in a position of having to compete for the same market, the hospitalizing physician. It is unknown to what extent acquisition of hospital technology is important in motivating physicians to select a particular hospital, but anecdotal evidence suggests that pressures for specific technologies, such as CT scanners, coronary care units, and cobalt radiation units, are substantial and account for considerable redundancy in technologic facilities.[50]

Further, many of these new technologies tend to be additive rather than substitutive. For example, a CT scanner was introduced at George Washington University Medical Center in 1973; by fiscal year 1976 the center was performing almost 4,000 CT scans. While there was a major decrease in pneumoencephalograms, there was little change in the frequency of noninvasive procedures such as electroencephalograms and conventional radionuclide brain scans. The net result was an increase in revenue to the medical center of almost $1 million, 97 percent of which was attributable to the introduction of the CT scanner.[51]

In acute care hospitals, a desire for better diagnostic and therapeutic tools is being stimulated by a case mix of increasingly severe illnesses. A number of factors contribute to this shift: (1) an aging population, which by itself contributes to an increase of chronic and terminal diseases; (2) a declining birthrate, resulting in a decreased proportion of hospital discharges attributable to normal delivery; (3) the institution of coverage under the Social Security Amendments of 1974 for chronic renal failure, leading to an increase in the number of transplants and chronic hemodialysis programs; (4) utilization review pressures leading to decreased length of stay by admitted patients and perhaps preventing questionable admissions that might have filled hospital beds in previous years; (5) the introduction of trauma centers; (6) the increasing tendency toward aggressive cancer chemotherapy; and (7) a decreased rate of admissions for mental illness, a disease category that uses a relatively small proportion of acute care hospital resources.

The difficulty in making clinical decisions in the face of catastrophic illnesses in the acute care hospital has been summarized by Warner:[52]

> The unusual economic environment of the delivery of catastrophic illness care works with the "social contract" in medicine to encourage the use of innovative therapies, even before their efficacy has been demonstrated and often irrespective of their costs, in striking contrast with the conventional innovation adoption process. The primary constraint on catastrophic illness treatment may well be the technology or the state of knowledge.

Given the combination of clinical desperation and current reimbursement procedures in acute care hospitals, the only limitation to growth in the technology market may be the availability of new technologies.

There is also a tendency to increase the pool of people eligible to benefit from new technologies. For example, a recent article in the *Western Journal of Medicine* stresses the excellent results alleged to have occurred in patients 70 years of age or older who received coronary bypass surgery.[53] The article was accompanied by an editorial by a cardiac surgeon who notes the increasing proportion of senior citizens in the population and concludes, "The message is clear: Age per se should not deter or delay the decision to recommend operation for properly selected patients disabled by ischemic chest pain."[54] The ethical decisions concerning rationing of technology are extremely difficult. It may not be reasonable to expect individual physicians to withhold technologies they perceive as valuable from any population, regardless of age or extent of coexisting diseases.

In summary, hospital costs are rising at an ever-increasing rate, and increased services (often technological in nature) are fueling much of this increase. Competition for patients and the desperation resulting from an increasingly sick case mix compel many hospitals to acquire new and expensive technologies, regardless of their proven efficacy.

The academic medical center

Academic medical centers in the United States play a special role in the development and use of medical technologies. Teaching hospitals experience to an even greater degree the pressures that affect hospitals in general. Also, as the major national resource for clinical research, academic medical centers play a dominant role in evaluating new technology and teaching its use.

Academic medical centers are divided into preclinical and clinical departments, the latter representing the various clinical specialties discussed earlier. Great departmental autonomy is the rule, with each clinical department usually operating its own clinical hospital service, undergraduate and graduate medical education programs, and research activities. Some of the larger clinical departments, such as medicine, pediatrics, and surgery, are further subdivided into disciplinary divisions, such as the division of gastroenterology, cardiac surgery, etc. These divisions themselves may have considerable autonomy. In fact, Petersdorf cautions that in departments of medicine:

> The divisional structure may lead to uncontrolled empire building, and a bright aggressive division head in an area that is well subsidized by the National Institutes of Health can readily promote growth of the division to unreasonable proportions.[55]

The budget of clinical departments usually derives mainly from departmentally organized patient care and research, rather than from a broader pool of institutional funds. Thus, the discipline-oriented department or division is the fundamental organization unit in academic teaching centers. These departments are often identified by the technologies they employ. Seldin cites as an example a department of medicine where 60 percent of departmental revenues derive from three clinical technologies: cardiac catheterization, electrocardiograms, and gastrointestinal endoscopies.[9]

Given the disciplinary organization of academic medical centers, it should come as no surprise that they often serve as the initial clinical testing ground for new technologies. For example, at the University of California, San Francisco Hospital three different manufacturers approached the department of radiology offering to donate a CT scanner in exchange for testing and evaluation.

Further, it is often in the direct personal interest of clinical faculty members to become involved in new technology research, since promotion and tenure decisions often are based heavily on research productivity. Our analysis of original and special articles that were published in 1976 in the *New England Journal of Medicine* reveals that 60 (31 percent) of the

196 original and 29 (17 percent) of the 172 special articles dealt directly with reporting or evaluating new clinical technologies. The senior authors in 79 (89 percent) of the 89 articles were faculty members at academic medical centers.

The extent to which the disciplinary nature of clinical departments and the organized institutes of the National Institutes of Health (NIH) serve to stimulate research in medical technology can only be speculated upon. Also unquantitated are the incentives arising from clinical income derived from evaluating new technologies such as the CT scanner. To the extent that these factors exist, they would seem to favor technology development and use. Further, there probably exist protechnology biases in the medical literature in the sense that it is easier to publish positive, rather than negative, results.[56]

The academic medical center also serves an important educational mission. It is the teaching site for undergraduates and graduate medical education and the main source of continuing medical education for community-based practicing physicians. Although it is difficult to compare the cost of medical care in teaching and nonteaching hospitals because of differences in case mix, there is good reason to suspect that resource use is more intensive in the teaching center.[41,42,57,58] The academic medical center is the style setter for medical practice. The fledgling physician is exposed to a highly technological style of medical practice that may be less appropriate for subsequent medical care in the community. Also, as noted earlier, a high proportion of resources used in tertiary care facilities is devoted to a relatively small number of chronically ill patients. Much of this resource use is in the form of compensating rather than curative technologies.

In summary, clinical academic departments are organized along the disciplinary lines and staffed by faculty who have a major personal stake in the evaluation of new technologies and in becoming specialists in the new areas. At the same time, these faculty members serve as leaders in determining patterns of practice because of their dominant roles in medical education and the medical literature.

Prospects for evaluating medical technology

It is tempting to wish for well developed methods to evaluate medical technologies, old as well as new. Precise technology evaluation would allow direct comparisons of marginal costs with marginal benefits for any individual technology or set of technologies. Then, after costs and benefits were assessed, comparison with other medical technologies as well as other competing nonmedical sectors of our economy would be possible. Without such methods, the forces in medical care discussed earlier will lead, all things being equal, to relatively indiscriminate development and use of many new technologies. The hope that such evaluation techniques can be developed and thereby assist in rationing new technologies can be found in the Office of Technology Assessment's (OTA) two recent studies on the assessment of medical technologies in general[59] and the CT scanner as a particular example.[60]

Unfortunately, there are formidable reasons, many of which are acknowledged in the OTA studies, to be pessimistic about the effectiveness of technology assessment in its present state. Four broad limitations deserve mention.

First, the methodologies available are primitive and disappointing. The OTA report lists at least four basic methodologic limitations:[59]

- The field is new and therefore lacks standard, usable methods.
- Medical technologies are diverse and complicated; standard formats for assessment therefore seem unlikely.
- Technology assessments are hampered by weaknesses in the tools and techniques of social science that must be used to calculate social impacts.
- Groups carrying out technology assessments have had great difficulty establishing boundaries for their studies.

These same methodologic limitations also apply to the assessment of the quality of medical care,[61 62] a measurement essential to the construction of a general format for medical technology assessment.

Second, technology assessment can be exceedingly costly and time consuming. For example, Coates found that the average cost of comprehensive technology assessments in 1972 was $381,000, with an average time span of 13 months.[63] McDermott describes why evaluation of medical technologies is so complicated:

> The costs of chance-selected control studies tend to be high because, in order to include enough cases to produce significant results, it is necessary to enlist the cooperation of hospitals geographically distant from one another; special systems may have to be created to transport specimens; additional personnel employed at the various hospitals to perform the necessary administrative or laboratory work; and the evaluation team must travel frequently and usually over long distances. Above all, there must be a central, and frequently traveling, directorate keeping a close watch so that each group will continue to make with care the detailed observations that are necessary, but that soon become dull and routine.[64]

The problems of constructing and implementing controlled evaluations of technologies, including drugs, are described in detail elsewhere.[65 66] There is a gross disparity between the amount of energy and resources required to demonstrate what a specific technology does as opposed to the amount needed to show how well it compares to other technologies.

Third, the territorialities of medical practice and medical research inhibit objective evaluation of medical technologies. Users of technology are apt to be biased in its favor. For example, the running debate about which type of mastectomy to use in breast cancer,[67 68] and the more recent controversies about coronary care units[37 69 70] and coronary artery bypass surgery,[71 72] are due in large part to a reluctance of the users to evaluate the technology (their technology) in question, which results in a paucity of good evaluative reports.

There are strong fiscal disincentives to technology evaluation by technology users. To evaluate a technology means to admit the possibility that the technology is not worth adopting. When introduction of a new technology such as the CT scanner into one medical center can produce a threefold increase in radiologic billings in two years, it is no wonder that there is a reluctance to conclude that the technology makes no difference to the patient.[51] The implication is that new technologies must be evaluated before market entry if they are ever to be assessed objectively.

The nature of research support, both public and private, is not conducive to technology evaluation. Of the estimated $4.5 billion spent on health related research in the United States in 1975, 61 percent came from federal sources, 32 percent from the private sector, and the remainder from state and local government.[73] The single largest United States biomedical research agency is NIH, which accounts for almost two-thirds of the federal expenditures for health research. The categorical nature of NIH, with its 11 separate institutes and its representative disciplinary study sections, plus the systematic incentives toward "protechnology" research described above, create powerful disincentives to cross-disciplinary technology evaluation.

Fourth, and most important, technology development far outstrips technology evaluation. McDermott has pointed out two reasons for this. First, many technologies, such as new surgical developments, are extremely difficult to validate; an innovation becomes established before its inadequacies are widely suspected. Second, while this necessarily cumbersome and lengthy evaluation is proceeding, new technologies continue to flood the medical marketplace. McDermott predicts that "medicine will soon find itself overwhelmed with new and unvalidated technologic interventions and be without possible methods to evaluate them."[64]

Thus, there are formidable obstacles to evaluation of current technologies, let alone technologies under development. Evaluation tends to be self-serving, to be oriented to process rather than outcome, and to promote the adoption of new technologies by both individual physicians and institutions.

Additional policy issues

Attempts to affect levels of technology development and use must deal with both low- and high-cost technologies (such as laboratory testing versus coronary angiography), diagnostic versus curative technologies (such as laboratory tests versus some types of cancer therapy), the ease of capital formation for the development and purchase of medical technologies, and the emphasis in the media on the benefits of medical technology.

Discussions of attempts to control medical technology have in the past dealt mainly with high-cost, diagnostic technologies. In our opinion, low-cost, high-utilization technologies such as laboratory testing, create more of a regulatory problem than do the "high-fliers." For example, Brook and Williams report a 39 percent increase in the use of laboratory tests during a two-year observation period of a New Mexico Medicaid population, a rate of increase in excess of all other components of medical care.[74]

How will regulatory mechanisms manage new curative technologies? Social pressure will be enormous for their development and use. An example of a low-cost, high-utilization technology currently under development, and for which utilization standards have yet to be deliniated, is the implantable electronic inner ear, a prosthetic device for those who are profoundly deaf, but whose auditory nerve remains viable. This is the first of many possible similar electronic prosthetic devices including possible visual and musculoskeletal prostheses, that have been made possible by the electronic miniaturization revolution.[75] Obviously, many different standards for its use must be formulated, especially the degree of hearing loss that would justify its implantation. The large number of potential consumers of this and similar technologies will certainly muster political pressure to see that it, and other prosthetic devices, are widely disseminated. The devices are being developed by private industry, and governmental control is minimal. They will eventually be relatively inexpensive, but we suspect will carry a large fee for diagnosis and implantation.

The pion accelerator is a very expensive ($10 to $15 million) device under development that, if perfected, may be used to destroy deep malignancies with much less damage to surrounding organs than occurs from current radiation therapy. A pion is a subatomic particle that decays after a specific time interval, releasing energy in the process. A linear accelerator is needed to produce these particles, which can be directed or aimed magnetically toward the malignant tissue. A pion can pass through skin and internal organs without harm before it decays. At the specific point of decay, tissue will be destroyed.

Once this device is perfected (we are familiar with at least one under development), it will probably be highly sought after by most large medical centers. Who will pay $15 million for it? When we asked this question of a vice president for leasing of a large financial institution, he said that his company would consider buying one so long as two criteria were satisfied. First, he would have to be convinced that it would not become technically obsolete during the span of a normal five-year lease. Secondly, he would have to be shown that the reimbursement rate for a treatment would be high enough to repay the loan (or lease).

Once perfected, this device theoretically could be demonstrated to be more efficacious than a CT scanner. The CT scanner is, in a sense, just a very sophisticated diagnostic device. A pion accelerator is a new treatment. Withholding payment for a device that increases diagnostic accuracy from 95 percent to 99 percent may be possible, but withholding payment for a treatment and potential cure for certain types of cancer will be extremely difficult to deal with openly as a matter of public policy.

Next, we would point out the relative ease by which capital is formed to finance development and acquisition of new technologies. This is an area in which the medical care system has been protected from the effects of a free marketplace. The two primary reasons for this are tax advantages and the certainty of payment for medical services.

Development of new medical technologies is often done in the private sector, as was the case with such devices as the CT scanner, the continuous blood flow analyzer, and the electronic prostheses mentioned above. The federal government then often subsidizes the purchase of these devices, either directly through grants, or indirectly through the tax-free nature of the municipal bonds that pay for public hospitals. Private industry is indirectly subsidized through both depreciation and an investment tax credit of 10 percent of the price of equipment purchased. Given the certainty of payment through current reimbursement practices, high-cost medical equipment is now purchased by financial institutions and leased to medical care institutions. For instance, one large financial institution we are familiar with now owns eight CT scanners and overall has over $125 million invested in medical diagnostic equipment that it owns and leases to others.

Finally, rarely a week passes without the heralding by *Time* or *Newsweek*, or *The New York Times*, or Walter Cronkite, of the development of a new means of diagnosing or treating disease. (For example, the May 23, 1977 issue of *Newsweek* recommended routine EKG stress testing (CRVS reimbursement value $105) for all joggers over the age of 40.) The public is rarely told of the problems involved in evaluating these new technologies, or of the current clinical disfavor in which particular technologies are held. When the public's desires for equity and access are added to these raised expectations, rationing of services becomes politically difficult, if not impossible.

The effect of the media on increasing public and professional interest in new medical developments was emphasized by Ingelfinger in a recent editorial in the *New England Journal of Medicine*:[76]

> In short, the cost of medical care may be increasing phenomenally, but the rate of its ascent is modest as compared to the steep incline of public interest in medicine, and the blast that sustains this soaring flight is supplied in large part by the activities of many news media. Comparisons of the *New York Times* Index for 1965 with that of 1975 indicates that the *Times*, in 1975, carried about four times as much medically related news as it did a decade earlier.
>
> The past 10 to 20 years have also been marked by the mushrooming of giveaway publications addressed to health professions. Among giveaways established since 1960 are *Medical World News, Medical Tribune, American Family Physician, Hospital Practice, Family Practice News, Patient Care, Emergency Medicine, Consultant, Current Prescribing, Internal Medicine News* and *Private Practice*. This is just a partial list, but the magazines I have listed, as a group, send out issues to over 1,300,000 potential readers, most of them physicians.

Thus, any controls over technology must deal with clinical, social, and economic forces that exert extreme pressures for the development and use of medical technologies before their necessity, effectiveness, or efficiency can be determined. Particularly difficult issues will be how to deal with new curative technologies for which there will be great social and professional demand, how to affect the use of technologies already on the market and widely used, and how to develop the political consensus needed to ration medical technology use.

Policy options

Most of the policy options for better resource allocation are cost control measures. They are directed more toward the supply of medical services than toward the demand for their use. Their impact on the acquisition and use of medical technologies has been minimal to the present time. The future may be more promising, if mechanisms currently in place are made to work together in a more coherent manner. The following is a discussion of the major policy options, their record to date, and possibilities for the future.

Capital expenditure regulation

Capital regulation is a relatively new mechanism intended to limit the growth of the cost of medical care through regulation of capital expenditures for new services, equipment, or facilities. This type of regulation is based on the belief that duplication of services should be discouraged and planning for new services should be rationalized. Since there is, theoretically, an almost inexhaustible supply of patients who could be given various medical services, a limitation on the supply of services will force the medical care system to decide which patients most need to use these resources. The usefulness of capital regulation as currently enforced to rationalize expenditures for medical technologies depends above all else on the issue that the specific technology has an acquisition cost, or results in additional services, that exceed a specified limit. There is no consideration of the operating costs attached to the acquisition.

How well does capital regulation work? Hellinger, in a recent analysis, states that there is no evidence that Certificate-of-Need capital regulation has significantly lowered total hospital investment.[77] In a more detailed analysis, Salkever and Bice say that Certificate-of-Need regulation "did not reduce the total dollar volume of investments but altered its composition, retarding expansion in bed supply but *increasing investment in new services and equipment.*"[78] [Emphasis ours.] Several critics make the point that capital regulation serves mainly to protect existing facilities from competition by restricting investment in alternative, less costly delivery systems (such as surgicenters),[77] as well as in the building of new hospitals.[78] Havighurst also points out that entry controls are often adopted because they are in the interests of the regulated firms themselves.[79]

How does capital regulation impact on medical technology? If, in fact, capital regulation tends to divert investment from a few large expenditures to several smaller ones, then it will tend to promote the purchase and possible overutilization of "lower cost" technologies (i.e., those costing less than $100,000 per piece of equipment). Also, private physicians' offices are specifically excluded from the regulations issued by the Department of Health, Education, and Welfare on January 21, 1977, specifying Certificate-of-Need requirements under the National Health Planning and Resources Development Act of 1974 (P.L. 93-641).

Past efforts at cost control through capital regulation were greatly hampered for a variety of reasons. Planning agencies were underfunded, did not produce objective plans to use as a basis for review, tended to be dominated by the institutions they were reviewing, and, most important, had little or no incentive to challenge the medical establishment. The

National Health Planning and Resources Development Act provides an opportunity for restructuring both state and local agencies. The greatly increased funding of the new Health Systems Agencies, the much greater specificity of functions and criteria to be utilized, and the increasing concern about the rising costs of medical care, may be a stimulus in the future to a more critical review of proposed new services. However, in the absence of extreme pressure from either federal or state government it can be argued that capital expenditures will continue unabated. The recent proposal by the Carter Administration to limit capital expenditures nationally could have a very significant impact if enacted by the Congress. In the absence of such a limit, it is doubtful that planning agencies have either the incentive or the clout to reverse current trends.

Thus, capital regulation has not been especially effective in the past. It may be effective in the future if it can force the medical care system to adopt a rationing mechanism, but this in turn will raise the social issues of access and equity.

Reimbursement policy

The physician. As was explained earlier, there are definite financial incentives for the physician to order ancillary technological services. There are also empirical data suggesting that these incentives do, in fact, operate to increase production of ancillary services.[80 81]

If control of medical technology is to be based, at least in part, on changing the patterns of physicians' ordering and performing of technological services, reimbursement mechanisms that now favor the ordering of these types of services must be changed. Very little effort has been expended in the area of adjusting physician reimbursement rates to counteract the built-in incentives to order technological services. If these built-in incentives are not changed, and if one assumes that the individual physician will continue to be able to order specific procedures and tests on the basis of his or her own judgment, then it seems to us much less likely that any other mechanisms devised to allocate resources will be successful. However, an obvious starting point to change these incentives would be to lower or eliminate reimbursement through federal health financing programs for services judged (by a mechanism as yet to be determined) to be either lacking in efficacy or inefficient.

The hospital. The principal means being contemplated to slow the inflation in hospital costs, and indirectly the investment in new technology, is cost control through prospective reimbursement. In the past, hospitals have been reimbursed on the basis of costs incurred and have thus been able to pass directly to third-party payers the cost increases due to technology acquisition and use. Prospective reimbursement is intended to control this type of increase by presetting the amount of revenues a hospital may acquire in a given year, usually on the basis of an assumed constancy in case mix and admissions, possibly with a 5 to 10 percent increase built in to account for inflation. The recently announced 9 percent increase lid on hospital revenues,[82] like the earlier Economic Stabilization Program's Phase IV controls,[83] is basically a prospective reimbursement plan.

Most of the relatively large literature on the various prospective reimbursement experiments centers around the specific issue of cost control, but here we are concerned only with how prospective reimbursement will affect the acquisition and use of medical technologies. Reports by Bauer and Denson and by Hellinger both make the point that hospital administrators do not currently control the utilization rates of ancillary service departments, such as radiology, pathology, physical therapy, or the inpatient medical services.[84-85] Sufficient technologies are already in place to cause huge increases in utilization, even without the acquisition of new, esoteric medical technologies.

Proponents of the prospective reimbursement system believe it will enable hospital administrators, who are the organizational entities who must be concerned with overall hospital revenue, to rationalize the hospital budgeting process in order to limit technology-related cost increases. In our view, this is a very difficult task because of the current organization of hospitals and their source of revenues. The hospital administrator simply does not now control the primary source of variable costs and revenues in the hospital setting, that of ancillary (often technological) services. However, a change in the structure of hospital organization, such as having the medical staff work with administrators to limit acquisition and use of technological services, may enable prospective reimbursement to work as an effective means of both cost and technology control. In a sense this is what happens in prepaid group practices.

Alternative delivery systems

Another approach to medical technology regulation would be to encourage the growth and development of alternative delivery systems such as health maintenance organizations (HMOs), which are constrained to operate under a fixed budget and must, of necessity, perform some rationing of technological services. Although HMOs are well known for medical cost containment, particularly in decreasing the rate of hospital use, less has been published concerning their use of medical technology. The diffusion of technologies into HMO practice lags behind the fee-for-service sector, but adoption of the technologies almost invariably occurs at some later date, as has been shown by recent experience with coronary bypass surgery in a large HMO.[86] However, stricter criteria for use of the labor-intensive technologies, such as gastrointestinal endoscopy, does lead to decreased use of these procedures,[87] and use of CT scanners appears to be less in HMO populations.[88] Also, Schovsky has data showing a decreased use of the low capital, high volume technologies in HMO settings in comparison to fee-for-service practice.[89]

Thus, while HMOs must respond to the medical marketplace and to customary practice, they offer a model of an alternate approach to resource decision making. The disappointingly low response to the implementation of the HMO act of 1973 (P.L. 93-222) (less than 3 percent of the U.S. population is currently enrolled in an HMO) suggests that the encouragement of growth and development of alternate delivery systems by itself is not a promising national approach to the control of medical technology. However, any new system that requires an economic ceiling and rationing may want to look more to the prepaid group practice model as an alternative for resource allocation decision making.

Manpower policy

Earlier it was shown that the trend toward medical specialization is linked directly with the availability and use of specific medical technologies. It follows that policies that influence the number and specialty distribution of physicians can be expected to have a direct impact on the use of medical technologies. This is particularly true of the high capital (i.e., CT scanners) and high labor (i.e., gastrointestinal endoscopy) technologies that tend to be restricted to specialists, and less true of the low capital, high volume technologies that apply to all categories of physicians. Because spread of new specialty-linked technologies seems to proceed until the field is saturated, the concentration of physicians would appear to be an important limit to the degree of technology diffusion and use. Indeed, new technologies are sometimes alleged to cause manpower deficits, as with the "shortage" of neuroradiologists consequent to the spread of CT scanners.

While the specialist-to-generalist balance is a factor regulating high cost technology use, the overall supply of physicians is an important determinant of the use of low cost technologies. The opportunity to generate income from the sale of ancillary lab tests[60] plus the probable targeting of physician income irrespective of physician density[61] means that technology use is directly related to physician supply. Eli Ginzberg quotes Canadian and American estimates that the addition of one physician adds approximately $250,000 to the net annual operating cost of the health care enterprise, much of which is due to technology use.

Although regulating the number and type of physicians is an important aspect of decisions that affect medical technology acquisition and use, it must be remembered that the long lag time required for physician training limits this strategy to a long range solution.

Utilization review and quality assurance

Utilization review and quality assurance include a variety of concepts. Our concern in this paper is the standard-setting functions of both as they apply to medical technology, particularly the process standards for medical care.

The history and literature on utilization review have recently been reviewed by Brook and associates.[62] They conclude that physician involvement in peer review has virtually no impact on costs of care, and that the length of stay approach to controlling hospital costs is ineffective. We agree with their suggestion that peer review of ambulatory care will "almost inevitably" lead to greater use of services and increased costs.

Professional Standards Review Organizations (PSROs) are a formal mechanism for both utilization review and quality assurance for patient care reimbursed by federal funds. PSROs were mandated as part of the 1974 Social Security amendments (P.L. 92-603). The statute requires that PSROs determine whether care was medically necessary, of recognized quality, and provided in the proper facility or level of care (inpatient, outpatient, etc.). The legislative intent was primarily one of cost containment (to avoid unnecessary services), but possibly for political reasons the administrative interpretation of the statute by the DHEW has leaned more toward quality control.[91]

Because PSROs must determine what quality care is, and thus be able to evaluate whether a particular procedure and/or service is necessary for a specific condition, their impact on the acquisition and use of technology may be extremely large. Yet, as now structured, they do not have the means to evaluate procedures and services themselves; they must rely on evaluations by others. As Gaus and Cooper have pointed out, "If technology assessment is not provided, then current practice becomes accepted practice."[92] Also, as mentioned earlier, most technology evaluation is done by persons with a vested interest in the technology.

Nevertheless, by defining a service as necessary or unnecessary, a PSRO defines both minimum and maximum levels of technology use. Havighurst and Bovbjerg discuss this point:

> . . . The very authority to define medical necessity includes the power not only to determine that some services are unnecessary and should not be rendered but also to determine that others are necessary and must be rendered.[93]

In our opinion the key to the usefulness of the PSROs is the power they have to define necessary services. As now structured, PSROs can go little beyond defining the necessity of a service on the basis of community standards, or others' definitions of efficacy. However, their contribution would be enhanced greatly if the PSRO mechanism at the national level developed a process of technology evaluation and standard setting. The National Professional Standards Review Council could be used for this purpose, assuming a change in its composition to make it less provider dominated. This would have to be done, however, in conjunction with the national health planning mechanism. In this way PSROs could become a positive force affecting both the acquisition and the use of medical technology.

Research policy

Earlier it was shown how increasing specialization in medicine combines with the disciplinary and categorical nature of medical academia and the NIH to create a research climate that is protechnology. One policy response would be to urge that an increased proportion of federally sponsored research be devoted to technology evaluation and cost-benefit assessments.

However, while this strategy might be argued as a way to increase the quality of medical care, it has at least two limitations as a regulator of technology use. First, much biomedical research is sponsored by nonfederal agencies. Indeed, the CT scanner was developed commercially in the United Kingdom. The degree to which commercial technology developers may concentrate on the medical market is illustrated by a recent prediction that medicine will be the single biggest target industry for computer applications in the future.[94] Second, as mentioned earlier, technology evaluation using available methods is exceedingly difficult.

Reducing or redirecting governmentally sponsored research will have only a minor impact on technology development and use in the foreseeable future. A mechanism that could have greater impact would be to require that a social, clinical, and economic impact report be made public before the federal government could fund new clinical or developmental research. This report could then be reviewed in a forum that is separate from the NIH, or other sponsoring federal agency.

Medical liability procedures

Few reports or empirical studies document the impetus to perform medical procedures that results from fear of possible future litigation. However, it seems rather obvious that many physicians may have shifted postures from, "If it can help and can't hurt, do it," to "If in doubt, do it, as it may avoid a future liability suit."

There are some inferential data in this area. Jonsson and Neuhauser observe that "the volume of X-ray and laboratory tests in Swedish hospitals is about half the amount ordered for similar patients in American hospitals."[95] This is in the context of medical services provided by the state and a structured grievance redress system, with litigation as a last resort.

There are also indications that the "malpractice crisis" is changing the way in which physicians practice. A.L. Lipson of The Rand Corporation (as reported in *American Medical News)* noted in a recent study that the malpractice issue may have conflicting effects on the use of medical technology. While, on the one hand, "some physicians are becoming more wary of performing 'high-risk' procedures or of dealing with patients they regard as inclined to sue, on the other hand some physicians are performing more diagnostic tests than would otherwise be necessary."[96]

Defensive medicine, that is, ordering procedures and tests with an eye more on future litigation than on the patient's current health status, does have an effect on the use of medical technology. While we have seen little direct evidence as to the degree of that effect, we would judge that it is in the direction of increased use of diagnostic tests. Regulatory mechanisms designed specifically to determine the efficacy of procedures and services, and to define situations in which procedures and services should be provided, should lessen the use of unevaluated services prompted by the threat of litigation. Reform of the medical malpractice laws to lessen the threat of litigation would have the same effect.

Medical devices regulation

Until recently, medical devices were developed and spread throughout the medical care system before evaluation was attempted. Of the several reasons discussed above, possibly the most important is the difficulty of designing and performing adequate experimental trials of medical devices. On the other hand, the Food and Drug Administration (FDA) has required that drugs be tested and proven safe and effective before they are marketed. Thus, evaluation of new drugs has been paid for directly by private industry (and only later indirectly by consumers), while evaluation of medical devices is paid for directly by the medical care reimbursement mechanism through payment for unevaluated technologies (such as the CT scanner and coronary bypass surgery). However, this may change due to the recently enacted Medical Devices law.

This law now gives the FDA many of the same powers over new and current medical devices that it has had over drugs. It broadly defines a medical device as an instrument or apparatus related to the care, mitigation, or treatment of disease. The law also establishes three classes of devices, with only one subject to premarket standards clearance. Class I devices will have only manufacturing and marketing controls applied to them to assure that the product meets minimal standards of quality and safety. Class II includes the Class I controls but adds specific performance standards. Class III also requires premarket clearance for both safety and effectiveness. The last classification is potentially the strongest mechanism we have addressed in this paper for the eventual control of medical equipment technology. However, it remains to be seen what type of regulations the FDA issues to enforce this law.

The law is primarily concerned with the safety and effectiveness of devices. It does not relate to either cost or utilization. Obviously, if a device has a relatively low cost, is proven safe in independent trials, and is used in a private physician's office, then neither this law nor capital regulation will affect its acquisition and use. There is also the question of how strict the FDA will be in classifying devices in Class III. Preliminary indications are that specialty panels empowered by the FDA to perform this classification have tended to place devices in the lower classifications that do not require evaluation of effectiveness. If the FDA chose to exercise the full powers conferred by this law, it could be an especially useful means of controlling market entry of new medical devices, although only if the reimbursement mechanism were coordinated with denial of payment for services that depended on nonapproved devices. (However, the law does not affect use of new procedures or services unrelated to a specific device.)

Fiscal ceiling on medical care system

A fiscal ceiling on the whole medical care system may be necessary to permit many of the above policy options to work. It is an obvious way to force national or regional decisions on resource allocation and the acquisition and use of medical technologies. Setting such a ceiling would require political and social judgments about the appropriate amount of resources to be devoted to medical care, and about the role of the many other factors influencing national health.

Perhaps the greatest problem with the fiscal ceiling concept has been the lack of ideas about how to attain it, how to make the national decisions governing it, and what a system would look like that incorporated it. With a ceiling on national expenditures for medical care many of the mechanisms we have discussed previously could be changed and made to work together more effectively. We caution, however, that while this option opens up many possibilities, it will also be the most difficult one around which to develop a political consensus.

Conclusion

This conference has looked at specific technologies and mechanisms for their control. In the end, however, we must be concerned with the cost of medical care, appropriate resource allocation, and ways to improve the health status of the American people. Payment for services must be based on a judgment about the social need for that service, not on the so-called medical marketplace. Our piecemeal accounting practices and nonrational economic system encourage expenditures for many services that contribute only marginally to improving our national health status, the cost of which is added up only at the end of the year as national expenditures. One of the strengths of our system is its diversity. Any system designed to allocate our resources must encourage the use of clinically necessary and economically efficient medical technology, while at the same time allowing for enough diversity to permit decisions to be made at the regional level on what methods and equipment should be acquired and used. This may require governmental authority to determine a reasonable economic ceiling on the system and formulate methods to enforce this ceiling.

The high cost of medical care is the result of a variety of factors. In our judgment, trying to control cost solely through technology control will result in discouraging the development and use of many beneficial technologies. Rather than seeking solely to control costs, a system must be created to evaluate the social, clinical, and economic costs of medical technologies, to encourage technologies that are efficacious and efficient, and to discourage those that are unevaluated or harmful.

Our current mechanisms are more flawed in application than in theory. For instance, the PSRO mechanism could be expanded to include technology evaluation. Health Systems Agencies could have greater effect by including Medicare and Medicaid reimbursement under their regulatory power. The FDA's regulations concerning the market dissemination of new medical devices could be coupled with reimbursement controls through federal health care financing programs. The National Health Planning Council (when it is formed as required by the National Health Planning and Resources Development Act of 1974) could assume its responsibilities toward technology evaluation as mandated by that act. It might then function as a "court of appeal" for decisions made at a local level concerning medical technology. The NIH or other federal agencies could be required to issue a social and economic impact statement before funding development of a new medical technology.

Efforts to determine appropriate technology development and use must take into account social and economic, as well as clinical, values. Technology by itself is not the culprit in the high cost of medical care; rather, it is our current inability to make and enforce decisions about what medical services we need and can afford. These are essentially social decisions, and, in the face of the forces that promote the acquisition and use of medical technologies, they must be made in the context of a political consensus concerning both medical care priorities and resource allocation. It is our judgment that without such a consensus, the forces that promote technology use will be difficult, if not impossible, to control.

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Regulatory and nonregulatory strategies for controlling health care costs

Alain Enthoven and Roger Noll

Health care is one of the most rapidly growing parts of the American economy. Real age-adjusted per capita spending on health care rose 55 percent from 1965 to 1975.[1,2] The largest single part of this increase is accounted for by hospitals; during the same 10-year period, real age-adjusted per capita spending on hospitals increased 80 percent. By 1976, spending on hospital care had reached $55.4 billion, or 40 percent of total health spending.[1] Consequently, the principal focus of public discussion of health care costs has been on hospital services. Recently, the debate has centered on the use of new medical technologies by hospitals and excessive use of hospitalization, especially for surgery and diagnostic testing.

The rise in hospital spending has several possible explanations. One might be that consumers can now buy better health than they could in the past. Higher incomes enable consumers to purchase more medical care, just as higher incomes lead to increased consumption of other goods and services.[3] Technical developments that make health care services more effective in treating illness also increase the demand for medical services. If these factors were the primary force driving up medical expenditures, a rise in medical expenditures should be associated with improved health. But the large spending increases of the past decade do not appear to have produced a corresponding improvement in the overall health of the population, at least as measured by aggregate indicators of morbidity and mortality. Bunker,[4] Lembke,[5] Wennberg,[6] and others have noted wide variations in the per capita consumption of certain health care services among similar populations without any apparent difference in medical need or health status. Gaus and associates found a large and significant difference in hospital and surgery utilization rates between Medicaid beneficiaries who are served by group practice Health Maintenance Organizations (HMOs) and control groups served by fee-for-service physicians; there was no significant difference between the study groups and their controls in terms of perceived health status, number of chronic conditions, or disability days per month.[7]

Another cause of rising expenditures could be that medical care improves the quality of life in ways not measured by aggregate statistics on health status. While this may be important, it is not readily measurable, and, in any event, the rising public concern about increases in medical expenditures suggests that at least some of these gains in the quality of life are probably not worth the costs.

A third, and probably the most important cause of rising medical care expenditures appears to lie in the incentives that have been created by changes in the way services are paid for. The share of hospital costs paid directly by consumers declined from 49.6 percent in 1950 to 8.9 percent in 1976.[1, 8] In 1965, government paid 24.5 percent of total health care costs; by 1976, the share was up to 42.2 percent.[1] The main purpose of the government programs was to increase the amount of services to target groups such as the elderly and the poor. The source of increased care for target groups was intended to be a net increase in real resources devoted to health care, rather than reduced care for the remainder of the population. So it is not surprising that health care spending has increased faster than total income; indeed, had the results been otherwise, such programs as Medicare and Medicaid could only be deemed failures. But the government has succeeded in increasing substantially the amount of medical services provided to these target groups. In 1976, Medicaid, for example, made per capita expenditures on medical care for the 23.2 million Medicaid recipients that nearly equalled average per capita spending by the rest of the population.[9]

The insulation of the patient from the direct financial consequences of hospital treatment eliminates most of the incentive that a doctor or patient might have to make sure that treatments are worth their cost. To the extent that providers and patients respond to financial incentives, treatments of low or uncertain value will be applied more frequently if neither the patient nor the doctor is financially responsible for the costs.

In theory, government or private insurers could try to prevent spending on medical care of low value by carefully monitoring the diagnosis and treatment of each patient and reimbursing only expenditures for treatments of significant medical value. Such close monitoring would require substantial administrative expenditures and much second guessing of professional decisions. Even if the costs of such an endeavor were worthwhile, private insurers would have little to gain from undertaking them. In most cases, insurance premiums are experience rated, so that, in effect, the cost of additional claims paid is passed on to the group paying the premiums. Moreover, government and employers tend to evaluate the efficiency of claims processors by the percentage of premium revenue that is absorbed by administrative cost, not by success in overall cost control, and to monitor treatment would increase administrative cost. In any case, if one company were to attempt such a procedure, medical professionals might refuse to cooperate, or indeed even decline to accept patients with policies from that company.[10] Without the cooperation of physicians, assessing the efficacy of medical treatments is an impossible task.

The position of the government toward trying to monitor the care of patients is in some respects stronger and in other respects weaker than that of insurance companies. Since patients aided by government are generally poor, providers have little chance of extracting payment from the patient should the government refuse to allow a particular cost. Moreover, government is a much larger purchaser of medical care than any private insurer, and its decisions, therefore, can have a greater impact on the economic viability of a provider. Nevertheless, government, too, must depend on voluntary cooperation among providers in order to obtain service, and cannot tolerate massive refusals by providers to serve patients whose bills the government has promised to pay. Moreover, government is bound by procurement rules, designed to prevent favoritism and fraud, which constrain the use of individual judgment. These rules are influenced by political pressure from well focused provider interests.

Because of the difficulties of effectively monitoring treatment, both government and private insurers rely on physicians to determine treatments and to establish peer review as the mechanism to curb spending on treatments of no value. Because all doctors and patients face essentially the same pattern of weakened incentives to consider the costs of alternative treatments, standard medical practice can be expected to include an ever growing array of accepted procedures that have a low or uncertain value. Thus, reimbursement of the costs of standard treatment will lead to ever increasing expenditures on medical services yielding little benefit.

To date, three types of policy response to the problem of rising health expenditures have been proposed. One is to increase greatly the share of medical costs that is paid by the patient, so that consumers will have much more incentive to economize on medical services.[11] A second is to leave intact the incentives for increasing expenditures in the fee-for-service, cost reimbursement, third-party intermediary system, but to impose economic and technical regulation on providers in an attempt to prevent the incentives from producing their natural effect. The third is to restructure the delivery and payment system in a manner that alters the basic financial incentives facing providers so that they find it in their interest to provide good-quality but cost-effective care. The main thesis of this paper is that spending on health services cannot be effectively controlled in the present political context without a policy of the third type.

Reliance on consumer cost-sharing

The first alternative, placing the whole burden of economizing on the patients by greatly increasing the extent of consumer cost-sharing, is not practical because it is incompatible with the objectives of both private insurance and public policy towards medical care. A large increase in deductibles and coinsurance rates would increase the risk that a family would suffer serious financial loss in the event of major illness. When applied to government programs that are aimed at lower income groups, it would also reduce access of the target population to medical care. Of course, the purpose of insurance is to prevent serious financial loss, and the purpose of the government programs, besides providing additional protection against serious financial loss, is to guarantee all citizens access to needed care, regardless of ability to pay.

To adopt a system in which patients must pay directly a much greater share of medical care expenditures is to conclude that society has picked up an overly generous point along an immutable trade-off between an equitable and an efficient health care delivery system. The evidence suggests that Americans are not yet ready to accept this conclusion. A good indicator of the political acceptability of this approach to cost control is the fact that proposals by the Nixon and Ford Administrations to increase cost-sharing by Medicare beneficiaries failed to attract a single Congressional sponsor. In the current political climate, any policy emphasizing more coinsurance inevitably will include an upper limit on a family's health care spending, above which all or practically all will be paid by insurance. At that point, the incentives in the fee-for-service, cost-reimbursement, third-party intermediary system would continue to work as before. The effect would be to pull medical care resources out of primary care and into catastrophic care to an even greater extent than is the case today. This means even less emphasis on activities that can help prevent disease and add significantly to the quality of life, and more emphasis on care that offers small net marginal benefits at very great cost. In addition, a shift to a system of catastrophic insurance would not merely be a financial device for reassigning risks; it would also mean a further reallocation of health care resources towards categories of care (such as long-term hospitalization) that probably already account for too high a share of health care expenditures.

Regulation as a substitute for appropriate economic incentives

A great deal of regulation is inevitable in health care. The debate over regulation is not a matter of all or none. The key issues regarding medical care costs are these: Is the purpose of regulation to stop or reverse the forces determined by the basic financial incentives in the system, or is it to channel those forces into socially desirable forms of competition? Will it attempt to overcome grossly inappropriate financial incentives, or will it merely modify the direction of financial incentives that are already close to being appropriate? Will regulators attempt "to make water run uphill," or merely attempt to channel the stream in its downhill course?

The significance of the distinction is this. The managers of regulated firms will make judgments about the benefits and costs of attempts either to change regulatory rules to their benefit or to evade them. If a regulator attempts to make the regulated behave in a way that is directly opposed to their financial interests, regulated entities will have a strong incentive to attempt to bend, fight, or evade regulations. This will force regulators to deal with many individual cases and will subject them to continuing pressure to grant exceptions to their general policies. If, on the other hand, the regulators attempt merely to modify the behavior of the regulated at the margin in such a way that the financial benefit to the regulated of changing or evading the rules is small, then one can expect fewer, less ferociously battled attempts to change the rules and fewer skillful attempts to evade regulation, for the potential gain will be less if these strategies succeed. In this case, regulators will rarely if ever directly threaten the financial survival of firms, and can manage these cases by exception.

This section focuses on the consequences of attempting to use regulation as a substitute for appropriate financial incentives. As used here, regulation refers to a type of social control of transactions that is characterized by its procedures as well as by its substantive purpose. There are two key characteristics of regulation. First, the regulatory authority is not a party to the transactions it regulates. Instead, it acts as the referee of transactions between other parties. By contrast, eligibility requirements and cost reimbursement formulas for Medicare or Medicaid recipients are not, in this sense, regulations, because they are written by the purchaser of the service. These controls are more properly regarded as terms of a contract between a purchaser and a vendor. While these controls are likely to be subject to the same kinds of political and legal problems that plague regulation, their development and promulgation is by an agency with a direct budgetary stake in the outcome. Consequently, the agency is directly accountable for the financial implications of its decisions, whereas a regulatory agency is not. Second, federal regulation is operated according to procedural rules that were developed from case law and formalized in the Administrative Procedures Act of 1946. The most important features of these rules are that decisions must be based on evidence that is presented in formal proceedings, that substantial evidence must be submitted in support of each decision, and that the courts may review a decision if it is appealed by a participant in the regulatory proceeding. By contrast, conditions on government purchases and subsidies do not have such elaborate procedural requirements. The formal procedures make the regulatory process expensive and time consuming. Moreover, the expense is greater as the number of regulated entities grows, so that the wisdom of regulatory intervention becomes in part dependent on the structure of the regulated industry.

An agency can regulate an industry either by dealing separately with each firm or each market (the case approach), or by writing general rules to simplify cases or to be applied directly to all firms in the industry without individual proceedings for each firm (the rule-making approach). In an industry with numerous firms, both approaches have important weaknesses.

The case approach to regulating numerous entities produces a situation in which many proceedings are underway simultaneously, all with different participants, evidence and proposed decisions. Because participation is costly, groups whose welfare is affected by many pending cases may not be able to afford to be represented in all proceedings. Yet, because policy is developed by precedent, each case can have important effects on cases involving completely different sets of producers and consumers. Moreover, the case approach undermines the development of consistent policy. Each decision depends on evidence presented in that case, and evidence is bound to vary from proceeding to proceeding. Evidence and policies developed in one forum will diffuse only slowly into other proceedings because of the informational problems that participants face in attempting to track the progress of many simultaneous cases.

The rule-making approach also presents problems. A rule-making proceeding, because it directly affects the welfare of many groups, normally will have many participants. Consequently, a rule-making proceeding usually takes several years before a decision is rendered, not counting the additional years normally lost in inevitable appeals through the federal court system. Moreover, general rules, based upon average conditions in an industry, will produce specific instances of inefficiency and inequity whenever firms and markets are heterogeneous. If the industry displays this heterogeneity, some firms will not find regulatory rules binding, while others will be threatened with extreme financial pressures, perhaps even bankruptcy, if they are forced to comply. While the former are likely to remain unaffected by regulation, the latter are likely to be provided with exception procedures.

The escape valve of an exception process and the procedural safeguards of administrative law serve the same equity objectives. The former saves the regulator from the embarrassment of protecting consumers so well that some are denied needed service! But it also blunts the effectiveness of the agency by instituting a mechanism which insures firms against financial failure and serves to drag out the regulatory process by extending it by one more phase. In addition, exceptions are always decided on a case-by-case basis, so that the extent to which an agency can rely on rule making as its main policy weapon depends on the degree of homogeneity among the regulated entities and the direct effect of the regulations on their financial health. Protracted proceedings with numerous pleas for exceptions are more likely to result from the regulation of price or product quality in a heterogeneous industry than from the imposition of informational requirements on the same industry, or the regulation of prices or product quality in an industry in which all firms produce identical products at identical costs.

The cost and effectiveness of regulation also depend upon the complexity of the information upon which regulatory decisions are based. The more complicated is the regulated activity, the more technical and detailed is the evidence that is submitted into the regulatory process. Complex information requires a more time-consuming process as well as greater costs for preparing, interpreting, and evaluating the data.

The problem is compounded if the objectives of regulation are themselves complex and lacking in concreteness. For example, "truth-in-packaging" regulations that require honest and complete revelation of the components of a product are easier to develop than are minimum standards of product quality. The latter are more susceptible to subjective determination and as a result require more careful and complete evidentiary proceedings in order to withstand judicial appeal. Similarly, while regulation of public utility monopolies is always difficult because the technology of public utilities is sophisticated, the most difficult issue is determining the quality of service and the level of capacity that the firm will provide. Once these are determined, the easier tasks are to calculate allowable costs and to develop a structure of prices that limits the ability of the firm to capture monopoly profits. In broadcasting, it is comparatively easy to determine whether a firm engages in fraudulent billing practices or broadcasts at the assigned frequency and power, but far more difficult to ascertain, as the Communications Act demands, whether the service provided by a broadcaster serves the needs and interest of the community.

Even in the absence of the complexities discussed above, regulation has proved to be of limited effectiveness as a mechanism for the social control of industry.[12 13] The procedural requirements of regulation give relatively well-represented groups with high stakes in the outcome a distinct advantage in influencing regulatory decisions, and the political obscurity of regulatory agencies tends to make them vulnerable to requests for special favors from politically active groups.

As a result, regulation is normally, on balance, beneficial to the regulated industry and harmful to its customers because the former tend to be better organized than the latter. The exceptions generally occur when the interests of consumers and businesses coincide, when the industry itself is divided, or when the agency is at the center of the issues that concern a mass political movement, such as environmentalists or organized labor. For example, product safety regulatory agencies are generally relatively effective in dealing with "bad actors" whose products are atypically dangerous compared to their competitors', but relatively ineffective — indeed, often pernicious — when setting standards for an entire industry. The industry-wide safety regulations that prove successful tend to be ones that are both inexpensive and noncontroversial, but that deal with problems that somehow escaped the notice of an industry, usually due to some informational problems, such as a very low frequency of harmful consequences from the industry's products or insufficient incentives for any particular firm to engage in the research necessary to solve the problem.[14]

When regulation is complicated by sophisticated data requirements, heterogeneous firms and vague objectives, regulators are especially prone to be protective of regulated entities that are on the verge of financial failure. When these complexities are present, the cause of a firm's financial difficulties is difficult to determine, so that a plausible case probably can be made that the regulator contributed to it. A political leader who helps to determine the fate of the regulatory agency through budgetary actions, legislative decisions, and unofficial nonstatutory oversight constitutes an informal route for a financially troubled entity to use to appeal agency actions. Politicians can be expected to be concerned if a firm in the home constituency appears threatened with extinction by regulatory actions. Thus, an agency may be punished by Congress or the Executive if it forces a truly inefficient operation into bankruptcy whenever the rectitude of its position is less than certain. However, it faces no concomitant penalty if it offers protection to the failing enterprise.

For all of these reasons, effective, comprehensive regulation is likely to be especially difficult to apply to the medical care sector. First, medical care is provided by numerous independent actors — physicians, hospitals, specialized care centers, other independent medical professionals. Second, a unit of medical care service is difficult to define and measure. The number of health problems is large, and the choice of treatment for each depends on individual physiological and psychological characteristics. Moreover, providers differ in the kinds and amounts of care they provide and in the treatment they believe to be best for a particular case. Thus, any regulatory intervention that promises to have a significant effect on the revenues or costs of providers — and thereby to threaten financial loss to some — will take the form of extensive case-by-case decisions (perhaps in the form of exceptions), with all the costs and deflection of policy that the case approach necessarily entails. In particular, attempts to control prices, capacity, and the quality of service by direct intervention are more likely to exacerbate problems in these areas than to ameliorate them.

In the medical care sector to date, the only economic regulation that has been thoroughly tested is the regulation of hospital capacity, and the results bear out the pessimistic conclusions of the preceding analysis. The federal government has attempted to control the number of hospital beds since the 1950s, when federal subsidies for hospital construction were made available to hospitals only if proposals to expand capacity were approved by area planning authorities.[15] In the 1970s, community planning has been giving way to Certificate-of-Need regulation by states in which a regulatory authority must issue a permit, based upon an assessment of community needs, before an increase in hospital capacity can take place. The available evidence indicates that Certificate-of-Need regulation has not succeeded in controlling the problem of overbedding. For example, a recent study[16] found that 30 of 41 states and areas that have such controls and for which complete data could be obtained gave approval for hospital beds in excess of 105 percent of their published need projection for five years hence. Fourteen of these began the period overbedded and approved additional beds, while five others became overbedded during the period studied as a result of the projects they approved. Other studies, using multiple regression techniques, have reached similar conclusions.[17 18]

The apparent ineffectiveness of Certificate-of-Need regulation is consistent with the preceding general description of the problems of regulating an industry as complicated as the health care sector. Regulators can be expected to have great difficulty in defining the appropriate number of beds for a community. Since providers can control occupancy rates, regulators cannot simply rely on observing whether beds remain unused. Instead, regulators must attempt to assess what bed use would be if all patients were given optimal medical care. Since optimal medical care depends on the particular characteristics of a patient, can be defined only by representatives of the regulated sector, and, in any event, is subject to wide variations in judgment among medical professionals, reaching a decision on this issue that varies much from existing standard practice is all but impossible. This was illustrated by the experience of the Committee on Controlling the Supply of Short-Term General Hospital Beds of the Institute of Medicine, a collegium of health care experts that, after five years of study, was unable to reach agreement on a standard for community bed needs. The committee was able to set an upper bound — four beds per thousand population — which they all could agree substantially exceeded the desirable standard.* Because the United States currently has 4.4 short-term beds per thousand population, the Committee could agree that the nation was overbedded, but could not agree on a standard that would have any measurable effect on hospitalization.[19] Considering that Kaiser Permanente of Northern California, a large prepaid group practice, operates at about 1.5 beds per thousand, the inability of the Committee to find a standard below 4.0 leaves much room for disagreement and uncertainty — and improvement in performance by the industry as a whole.*

Even if a target for the overall bed rate could be established, other issues are bound to be raised when a particular hospital applies for permission to expand capacity. Among these are the responsibility to expand service for a particular subset of the population, the desirability of letting a hospital of particularly high quality provide service to a larger population, the possibility of bringing an exciting new treatment to an area, and the certainty of employing more local residents in building and staffing a new facility. Since the relationship of all of these issues to the desirability of expanding a hospital is bound to be fuzzy, regulators are understandably reluctant to appear to be some peculiar form of ogre by preventing the performance of an important public service and the creation of jobs.

The third-party payment system contributes to the problem facing regulators. Since most of the cost of operating unnecessary facilities is likely to be paid by the federal or state government (Medicare and Medicaid), or by insurance policies that are experience-rated over an area wider than a Health Service Area, the communities that regulators seek to protect against rising costs (and hence, for political reasons, the regulators themselves) face weakened incentives to tip hard decisions in favor of cost control. This could be attacked by federalizing regulation of hospital capacity. But the result would be an enormously complex regulatory agency, undertaking to decide literally hundreds of Certificate-of-Need cases simultaneously. The agency would be forced to grant permits by formula, thereby overlooking legitimate special cases and community problems, unless the formula were overly generous, or to engage in so many independent decisions that coherent policy would be unlikely to develop.

Even if capacity regulation were to succeed in controlling the number of beds, it would still be unlikely to have much of an effect on costs. A hospital does not add beds for the single ultimate purpose of having beds, but as an instrument in achieving other objectives such as attracting more doctors, increasing the status of the hospital, or improving its ability to provide what the staff perceives to be good care. Because beds are not the only means for achieving these objectives, controlling beds is likely to lead primarily to an increase in other activities that also raise costs and demand further regulation.

*Four beds per thousand could be achieved by reducing excess capacity without reducing hospital days per capita.

*Kaiser Northern California's population is not typical of the United States. But, even when age-adjusted, their hospital utilization is about half that of the United States as a whole. The situation is similar among other prepaid group practices.

This is the familiar regulatory tar-baby effect.[20] Regulatory agencies, because of the nature of their design, must confine their activities to reacting to symptoms rather than attacking causes of a problem. If regulation is severely binding to a firm, the imagination of entrepreneurial managers generates continuing strategic actions that fall between the cracks of regulatory rules and defeat the purpose of regulation. The problem is most pronounced in an industry with numerous firms, for then the regulator faces a substantial problem in detecting the latest innovative response to existing regulations. The detection lag, when combined with the time involved in issuing effective regulations, produces regulatory activity that primarily affects the form and pace of innovation, but does not effectively achieve regulatory objectives.

Regulation to control the adoption of new technologies is not likely to be effective because it is even more susceptible to the same problems that make capacity regulation ineffective. Most new hospital services do not involve the use of expensive new capital equipment; instead they are new combinations and more intensive uses of services already provided.* Thus the opportunity abounds for an infinite variety of new technologies that represent changes in the way service is delivered, perhaps including new wrinkles that do not constitute a main part of the costs of the entire package of services.

The first job of the regulator in this milieu will be simply to detect the existence of new technologies. In principle, regulators can demand prior approval of technologies, but in practice, because many are rearrangements of existing treatment methods, the definition of a new technology will be obscure and, as a legal matter, debatable, so that the detection of new technologies will be an important activity. Because hospitals are so numerous — even large hospitals that are likely candidates for innovation number in the hundreds — detection will be difficult.

The problems of the regulator are compounded by the speed of diffusion of new technologies among large hospitals.[22,23] Computed tomography scanners are a good case in point. The first two CT scanning units in the United States were installed in mid-1973. Three years later (August 1976) 652 CT scanners were known to be in operation, had been approved, or were on order.[24] The rate of installation, averaging 20 per month from June 1975 to September 1976, is apparently accelerating as new companies enter the market. With such rapid diffusion, if more than a couple of years are lost in detecting a new technology and sustaining through appeal a regulatory finding that a treatment constitutes a new technology and therefore should be regulated, hundreds of hospitals already will have adopted the new technology before regulation of it begins. This places regulators in especially difficult straits. Will they impose financial losses on innovative hospitals that adopted a new technology before the service was legally defined as being one? Or, if use of the new technology is "grandfathered" but prevented from spreading, how will regulators cope with the incentive this creates for

*L.B. Russell, in a Brookings Institution document, has described the nature of several recent innovations in care.[21]

substantially more rapid rates of adoption of new technologies (in order to be grandfathered) and with the competitive advantage that grandfathered hospitals will have because they offer a wider array of services? Grandfathering is probably inevitable, but it rewards providers who move quickly to buy a new device before proof of efficacy and cost effectiveness is established, and punishes those who take a more deliberate approach.

Probably regulators will in fact allow nearly all new medical technologies. In part, this is the easy solution to the issues raised above. But in part, it is the natural consequence of placing the burden of proof on the regulators to find, if a new technology is to be denied, that it has no medical value. The problem of new medical technologies is typically one of overutilization, not of total ineffectiveness. Because providers and patients face weakened incentives to economize on medical care, treatments are encouraged to a point at which they have very low or no marginal value. Proponents of a new medical technology will provide long lists of examples in which it has provided great benefit to a patient. The important economic issue is not whether the technology should be used, but how extensively. This is inevitably a tricky issue of medical judgment that regulators are unlikely to be willing to second-guess. Once one hospital in a community is allowed to adopt a technology, the incentives will be present to use it to full capacity. This will provide hard evidence to support requests from other hospitals that they, too, need the new technology to provide the best care for their patients. Arrayed against data on medical needs and utilization rates will be arguments of principle, that a community does not really need more than a single hospital with that treatment capacity, that the hospital having the technology ought to realize that it is being overutilized, and that the sensible policy is for this hospital to share the use of it with doctors from other hospitals after cutting back its use on the hospital's own patients. Because regulators will not have hard evidence that the latter policy would be effectively carried out, they are likely to be extremely reluctant to deny a license for more investment in the new technology and, thereby, to assume responsibility for a demonstration in the future that their decision had led to unnecessary suffering and deaths.

At the heart of the problem of attempting to regulate the costs of medical care directly are two difficulties: (1) the tenuous nature of the connection between expenditures on medical care and health, and (2) the incentives that regulators inevitably face to resolve uncertainties in favor of the regulated entity. The latter arise from the nature of the regulatory process and the political pressures applied to agencies. When the issue is extra expenditures on possibly unnecessary care versus denial of access to life-saving treatment, doubts will be resolved in favor of the former, regardless of theoretical explanations about perverse incentives or after-the-fact cost-effectiveness studies of past regulatory decisions. Recent legislative actions to legalize laetrile in several states illustrate the essence of the problem facing any politically responsible person who would attempt to control the technology of medical care.

The significance of these lessons from regulatory experience will be illustrated once again if the proposal of the Carter Administration to put a cap on hospital revenues is enacted. While such a law might retard the rate of increase in spending for a while, it is likely to encounter severe problems in the long run. Indeed, even its short run effectiveness can be doubted. The Administration characterized the program as "transitional." The apparently temporary nature of the proposal must further weaken whatever incentive hospital administrations might have had to respond to the controls with fundamental, cost-reducing changes in management. In fact, for a year or two, ingenious hospital administrators may be able to appear to comply merely by making bookkeeping changes. For the longer run, an exceptions procedure must accompany the program, and when the cap really starts to bind, all the incentives to grant exceptions will be at work. In fact, this particular proposal was already emasculated at birth by the largest possible exception, the wage pass-through that was needed to get labor's approval of the measure. Moreover, hospitals will seek to avoid the impact of the regulation by "unbundling" services, such as by switching the billing—if not the provision, of many services from the hospital to the doctor. Regulatory countermeasures will be met by counter countermeasures, further distracting the attention of all from the cost-effective provision of needed and valuable services. Furthermore, under an across-the-board rule, such as a 9 percent limit on the annual increase in spending, some hospitals will find the rule more generous than their needs while others will find that it causes extreme financial pressure. Hospitals that find the ceiling to be overly generous can be expected to take the full 9 percent, lest they lose the right to a future increase based on present costs. (Note how this kind of regulation rewards those who were especially fat and punishes those who were especially frugal in the base year.) Hospitals that feel constrained by the ceiling can be expected to appeal for exceptions based on their particular circumstances. The courts, if not the regulators, will have to consider these appeals in detail on their merits. While tying up 1000 hospitals in court might not daunt some would-be regulators, temporary restraining orders may, by allowing the hospitals to raise their rates while the case is being litigated. Even if the proposal were ultimately successful at controlling total hospital spending at the stated growth rate, there would be no force in the system to motivate efficiency or equity in the allocation or production of services. At best, the hospital industry would simply add only 9 percent annually to its present wasteful and inequitable activities.

As pointed out above, the essence of the economic problem is care of very low or no marginal value. One element of eliminating such treatment is, of course, to identify them and to make patients and providers aware of their undesirability. Regulation could be used to serve this purpose. Regulators could be given the responsibility to evaluate treatments and to define and enforce informational requirements for providers and third-party payers. By itself, informational regulation is not likely to have much of an effect on medical care expenditures, since it would not alter the structure of incentives facing patients, providers and third-party payers. Nevertheless, information requirements are an important component of the reforms to be proposed in the next section of this paper.

In general, effective information regulation is easier to accomplish than regulation of prices, costs, and technology because it does not have to be burdensome to providers and is less directly related to the financial health of regulated firms and the physical well-being of patients. The main problem with informational regulation is that government officials do not particularly like it. For example, although the act establishing the Consumer Product Safety Commission gives informational requirements the same status as product standards as instruments for reducing injuries related to hazardous products, during the budgetary process Congressional committees have persistently cut back even meager requests for funds to pursue informational strategies. Usually these cuts are accompanied by remarks indicating the lack of faith Congress has in the ability of consumers to absorb and profit from better information on product safety.[14]

Part of the reason for dissatisfaction with informational strategies in safety regulation is the observation that some consumers continue to buy models and brands that are less safe than competing products after better information is provided. One reason for this behavior, of course, is that people do not attempt single-mindedly to avoid risks. Another is that safety usually is costly, so that consumers may judge that, after a point, added safety is not worth a higher price.

In the area of health care, the role of informational strategies will be quite different, at least initially, from the one they have played in consumer protection policies. As proposed here, informational requirements in health would be tied to an expansion of the number of options available to consumers for purchasing health care services. Institutional arrangements that provided care at lower costs by eliminating unnecessary services would be more attractive to consumers if the care provided could be shown to be as effective as more costly alternatives. In the beginning, informational requirements would serve to assure consumers that options with lower cost could be medically effective. In the longer run, informational requirements would provide additional protection, beyond existing accreditation and professional review procedures, against an erosion in the quality of care because of excessive competitive focus on costs. The specific form of informational standards in health must remain for medical experts to delineate, but the general nature of the information would be data on patient outcomes. Examples might be case fatality rates from heart attacks, adjusted surgical mortality rates, rates and disposition of medical injury claims, etc.

Information standards can affect medical expenditures only in conjunction with other changes in the health care delivery system. In particular, consumers must be given a variety of health care programs from which to choose, and some of these must be tied to new institutional arrangements between providers and payers that create incentives for cost control. The purpose of the next section is to outline the form these other changes could take.

Changing the structure of the medical care system

The two main alternatives to fee-for-service, cost-reimbursement, third-party financing are services provided directly by government with spending determined in the budgetary process, and services provided by cost-effective organized systems (i.e., health maintenance organizations and other systems that create incentives to economize), with total per capita spending determined in a competitive market.

Top-down budgeting may indeed bring total spending under control, but it has no built-in means for assuring that much useful output is produced. This is especially true of a medical care program whose output cannot be measured in any simple and adequate way. For example, at least by civilian standards, the Department of Defense operates and fills far too many beds. In fiscal 1974, hospital days of care for active duty military personnel, 95 percent of whom were males 18–44, were 1,887 per thousand personnel. The Military Health Care Study compared this to 611.5 days for noninstitutionalized U.S. males age 15–44, 204.8 days for Kaiser Northern California, and 559.4 days for nonactive duty beneficiaries of the Military Health Services System. Some of this difference may be explained by the particular conditions of military life. Moreover, because military and civilian utilization data may not refer to exactly the same thing, comparisons should be made with caution. But much of the difference is explained by longer stays for the same diagnosis. As the Military Health Care Study tactfully phrased it, "the incentives in workload-based programming may encourage relatively heavy use of in-patient care."

A recent National Academy of Sciences study of the Veterans' Administration system concluded that hospital beds were not located in accord with medical needs in different localities. The study found that about half the patients in acute medical beds, one-third of the patients in surgical beds, and over half the patients in psychiatric beds did not require or receive services for the specialized medical facilities that were associated with these types of beds.[25] The Veterans' Administration experience reflects a pervasive problem that government encounters when it tries to provide services directly to citizens. In the bureaucratic budgeting process, cutting back service to a subsidized group is politically hazardous, so that an agency can strengthen its case for more by doing a poor job with the budget it has. Moreoever, because budgeting in government is based on workload rather than capitation, its physicians face utilization incentives similar to those present in the fee-for-service system.[26] In our view, the problem of rapid and unproductive increases in spending for health care cannot be solved without altering these incentives through a fundamental change in the structure of the medical care system.

In considering proposals to restructure the medical care system, one must bear in mind that government seems unable to impose involuntary changes in the prevailing arrangements between patients and providers. The key features of the existing system, in addition to third-party financing, are the fee-for-service payment method and the use of a personal physician, selected by the patient, as a gatekeeper to the other elements of the health care delivery system. Any restructuring of the medical care delivery system probably must preserve the option for patients and providers to continue to operate under these arrangements. In part, there is a resistance to change from providers, since the existing system operates to their financial benefit. Rising medical expenditures are, after all, a source of rising income for providers. Moreover, the combination of the fee-for service, cost-reimbursement, third-party payment system and the use of the physician as gatekeeper reduces provider risks by eliminating the client's incentives to consider costs and by guaranteeing within broad limits that costs will be covered.

Also, patients can be expected to resist mandated changes in their relationships with providers, especially physicians. Information about the quality and effectiveness of health care providers and services is difficult for a patient to obtain and is gathered in part over years of experience. Moreover, the success of medical treatment may depend on the confidence that the patient has in the provider. For both reasons, patients will value relationships with providers that have developed over the years and will be reluctant to sacrifice them for the conjectural superiority of alternative arrangements. This is not to say that patients will not accept changes in the medical system; indeed, if the efficiency of the medical care sector is to be significantly improved, changes are necessary, and any reform depends upon flexibility on the part of consumers. If an alternative set of relationships is developed, the superior performance of the alternative can be expected to induce patients to switch, since switching physicians occurs periodically in any event in response to residential changes, unsatisfactory services, changes in age, or the retirement of providers. The point is that changes are acceptable if voluntary, but likely to be resisted if involuntary. Thus, the best hope for restructuring the industry is to facilitate competition between the fee-for-service system and alternative plans that are based upon per capita payments.

A competing, capitation-financed plan has two defining characteristics: (1) a group of physicians accepts responsibility to provide members of a defined population with substantially all necessary health services for a fixed per capita payment (based on age, sex, and other factors) that is set in advance; and (2) consumers exercise free choice from among competing systems of care, but if they elect a more costly system, they pay the extra costs themselves. Physicians control nearly all health care expenditures. They are by far the best qualified to make the difficult judgments about need and cost-effectiveness. So it makes sense to give them the main responsibility for controlling health care costs, provided that they make these decisions in an environment that generates incentives to use resources efficiently.

In such a system, the physicians as a group would not receive more money for providing more or more costly services. The competitive market holds them responsible for their total spending via the per capita payments; informational requirements and the freedom of consumers to switch to an alternative system hold them responsible for giving good service. Wide variations in organizational form and physican practice style can be compatible with operation within these principles; it need not be hospital-based, prepaid group practice. Among the competing types of organization, one might find Individual Practice Association Health Maintenance Organizations (HMOs), Variable Cost Insurance (VCI) plans, and what Paul Ellwood has called Health Care Alliances (HCA).[27 28] An HCA would be organized by an insurer, and would be associated with a limited set of hospitals and doctors designated by the insurer to deliver comprehensive medical care to the insurer's customers. As with an HMO, the premium for an HCA or a VCI plan would reflect the economic efficiency of the providers. Such organizational arrangements would not need to entail any sudden or drastic change in the practice styles of many providers. But, to be economically competitive over the long run, the organizations would have to develop cost controls that were effective and acceptable to consumers and providers. Health Maintenance Organizations now serve about six million people at total costs (premium and out-of-pocket) that are 10 to 40 percent lower than the costs of serving comparable people with third-party insurance. Most of the cost savings are attributable to hospitalization rates that are about 30 percent lower than the rates for insured groups that have similar socioeconomic and demographic characteristics.[29]

As argued above, physicians and consumers are accustomed to the fee-for-service, third-party intermediary system and would reject an attempt to change it suddenly and drastically. Nevertheless, if HMOs and other new arrangements are more efficient, they will gradually win out in competition with the fee-for-service, third-party intermediary system if given an opportunity to compete ~~on equal terms~~. A fair market test for HMOs is hardly a new idea,[30] but it still has not been seriously tried.

To begin to ameliorate (solve being too strong a word) the problems of open-ended government spending and the inflationary incentives of third-party financing, the federal government should replace its present commitment to fee-for-service, cost-reimbursement, third-party financing, reflected in Medicare, Medicaid, and tax subsidies for health insurance, with a system of fixed prospective per capita payments, related to predicted medical need and ability to pay, which beneficiaries are free to have paid to the private plan of their choice. In that way, the government would not be paying more on behalf of people who choose a more costly system of care.[31] People who preferred a more costly system would be free to elect it, but would pay the difference out of their own net, after-tax income.

Financial aid to individuals in such a system would be based on actuarial categories. A simple, familiar example is categorization by household size — individuals, couples, and families — for other than Medicare eligibles. A more complex system might be based on age groups, perhaps divided into ten or twenty year age intervals. Actuarial categories would be chosen to capture most of the predictable variation in medical need. Premiums would be determined by individual health benefits plans in a competitive market-place. The government would base its subsidies on actuarial cost, or the average cost per person or per family for covered benefits.

For people who are not poor, the Government would eliminate the open-ended tax exclusion of employer contributions and tax deductibility of individual premium contributions. These would be replaced by a refundable tax credit equal to some fraction (somewhere between one-third and two-thirds) of actuarial cost, and usable only for premium payments to a qualified health plan (defined below). This would produce gains in both efficiency and equity. It would replace today's marginal tax subsidy of 30 percent or more to health insurance, with a 100 percent subsidy up to a predetermined amount and no subsidy beyond that. Tax deductions that now provide the greatest subsidy to the best covered would be eliminated, and the resulting revenue would be used to put a floor under the least covered. Raising the after-tax cost of additional health benefits would motivate people to choose more cost-effective health plans.

For the poor, the Government would replace Medicaid with "health plan premium vouchers" that could be used only to pay premiums to qualified plans. The value of the vouchers given to a family would depend upon income, reaching 100 percent of actuarial cost for the very poor. The plan would be means-tested, integrated, and administered through a reformed welfare system. The amount given a poor family would be calculated to be sufficient to give them enough purchasing power to pay for a good health benefits plan. Plans would be allowed to compete for the business of the poor by offering additional benefits beyond those required of a qualified plan.

For Medicare beneficiaries, the concept could be implemented by changing Section 1876 of the Social Security Act (which governs payments to Health Maintenance Organizations) to permit each beneficiary to direct that the adjusted average per capita cost for his actuarial category be paid to a qualified health plan in the form of a fixed prospective periodic payment. A beneficiary could augment this plan by purchasing more comprehensive benefits, but without additional financial assistance, just as today roughly half the Medicare beneficiaries buy supplemental insurance. Medicaid supplements to Medicare beneficiaries would be replaced by means-tested vouchers.

The object of these changes would be to make it possible for everyone to benefit from economizing choices by obtaining lower premiums, more favorable cost sharing arrangements, or better benefits from a more cost-effective system of care. That possibility is denied to most people today.

A broad regulatory framework of devices designed to enhance competition should be coupled with the proposed financing system. The purpose of the regulatory framework would not be to stop or reverse the forces created by financial incentives. Instead, the idea is to do as much as possible to create financial incentives that would motivate socially desirable behavior, and to leave to regulation only an irreducible, unthreatening minimum.

The following regulatory proposals, while not a complete procompetitive regulatory framework, are advanced to stimulate debate and to give a general indication of lines that ought to be examined more thoroughly. The following are suggested requirements to qualify a program to receive the tax credits, vouchers, and Medicare per capita payments.

1. Open enrollment

Each qualified plan would be required to participate in a periodic (i.e., annual) open enrollment, patterned after that of the Federal Employees' Health Benefits Plan (FEHBP), and to accept all enrollees without regard to age, sex, race, religion, income, employment status, or prior health condition. This would give everybody something that few have today, a choice among several competing plans. Nondiscriminatory enrollment is designed to insure that plans succeed by offering better services at lower cost, not by selecting preferred risks. If the government can do a good job of selecting actuarial categories and base its per capita payments upon them, and if competing health plans base their premiums on the same actuarial categories, much of the profit from selecting preferred risks can be removed. Because there will always be other sources of variation in individual health risks, not all of the opportunity to insure only good risks can be eliminated. Therefore, at some point, health plans will have to be required to take their chances with risk; otherwise, poor risks would be uninsurable. An open enrollment requirement applied equally to all competing plans would help to spread the poor risks.

2. Community rating

Competing plans should be required to offer the same rates for the same benefits to all those in a given actuarial category anywhere in a market area. This requirement attacks the incentive to seek out preferred risks and combats other forms of discrimination.

3. Catastrophic limit

The amount of out-of-pocket payments that a family must make in a year would be limited. The ceiling might be related to income, and it might be high, i.e., $2,000. But a uniform, clearly stated limit would be required of all qualified plans. The reason for the limit is to assure that the health insurance will not be defeated and that people with serious illnesses will not become additional burdens on the public sector for lack of adequate insurance. In a capitation-based system, little is lost in terms of consumer incentives from having such a ceiling. While consumer cost-sharing may be one useful tool in motivating economy in the use of resources, it is primarily useful and probably politically acceptable when applied to consumer-initiated primary care and to the overall cost of a complete insurance package. It is much less effective and desirable, if at all, when applied to the costs of caring for very sick people. The federal government might reinsure qualified plans for catastrophic costs.

4. Information disclosure

To help consumers judge the merits of alternative plans, and to help assure public confidence in qualified health plans, disclosure of certain information should be mandatory. Uniform financial disclosure should be required, as the SEC regulations require of public companies. Data on patterns of utilization and availability and accessibility of services should be required, as now of HMOs. Each plan should be required to publish the total per capita cost of care by actuarial category, including premiums and out-of-pocket costs. The agency designated to determine whether a plan is qualified would have authority to review and approve (for accuracy and balance) promotional materials, including presentations to be included in the booklet available to all during the period of open enrollment, just as the Civil Service Commission now oversees the FEHBP. The administrative agency would have authority to review and approve the nature and contract description of options for additional coverage beyond the basic plan, the purpose being to assure that options either conformed to a standard contract or were described in a standard format with a manageable number of clearly worded additions and exclusions. This would force plans to publish their terms in a manner that was understandable and facilitated direct comparison among plans without making the consumer master a lot of fine print. Finally, the government should gather and publish information on the medical qualifications and, as the information became available, on the performance of providers. To the extent possible, these information requirements should be the same for all health benefits plans.

5. Premium setting by market area

As mentioned earlier, one factor that weakens the incentive of a local regulator to make decisions that will reduce health care costs is the knowledge that the premiums of many (probably most) of the citizens in the regulator's jurisdiction are based on experience over a much wider area. For example, plans like the Aetna and Blue Cross-Blue Shield options of the Federal Employees Health Benefits Program are experience-rated nationally. So higher costs in, say, Sacramento do not appreciably raise premiums there. This practice creates a serious barrier to competition. The ability of Aetna and Blue Cross-Blue Shield to compete against HMOs for federal employees in Washington, D.C., a high-cost area, is enhanced by the favorable experience of those carriers in low-cost areas, while HMOs have a similar advantage in low-cost areas. The HMOs, being local, must set premiums that are based solely on local costs. Competition would be enhanced if each carrier were required to set separate premiums based on local experience for each market area. One or several contiguous Health Service Areas would constitute a single market area for this purpose. This device illustrates the point that appropriate regulation can both enhance competition and improve the balance of incentives bearing on regulators.

Other regulatory policies that now apply to insurers and providers could be incorporated into the new scheme of regulation. Safeguards against fraud and abuse, conflict of interest, and all forms of discrimination could be a part of the program. In addition, a qualified plan could require that participating providers limit charges to approved fee schedules.

The goal of the preceding proposal is to reorganize the delivery system into competing organized systems. It could be defeated if health-care financing continued to be provided exclusively by third-party intermediaries, each paying fees and charges to all providers. Open panel insurance programs do not foster competition among providers to control costs. Rather, they continue to reward providers for cost increasing behavior. For the competitive approach to succeed, a large percentage of physicians must be allied with one or another competing health plan. The design of an appropriate set of rules to assure this must be complex, because, for example, it might be desirable for some specialists to work on referral for several plans. But some rules to prevent a noncompetitive outcome would be needed. A beginning along these lines would be to guarantee all consumers access to several plans that differed from conventional insurance. Currently employers who arrange and contribute to group insurance plans for their employees are required to offer membership in one or two qualified HMOs, if available, as well as normal health insurance. While this is helpful, it does not go far enough, for a choice between two or three plans does not allow the forces of competition to work to full effect. Instead, employer contributions should be applicable to membership in any qualified plan of an employee's choosing. Moreover, employers should be required to provide standardized information about all qualified plans that seek access to their employees.

The adoption of a program of competing health care plans would free consumers to choose the plan that, in their judgment, served them best. Consumers and providers who preferred to stay with the third-party intermediary system would be free to do so, but their decision would not continue to be subsidized by the government.

This proposal is not a finished plan. But neither is a proposal to create a regulatory authority which would be given a general mandate to control medical care expenditures. To our knowledge, no proponent of regulation of health care technology has yet described the mechanisms regulators are supposed to use to deal with "grandfathering," to provide exceptions, or even to define what constitutes a new technology. Anyone who advertises a regulatory scheme as the final word on cost control without addressing these issues is violating the rules of truth in advertising.

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Biomedical research and its technological products in the quality and cost problems of health practices

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Rising costs of health care and issues related to its quality and accessibility have focused attention on the role of biomedical research and the impact of new technologies. It is imperative that limited resources be allocated to attain maximum health benefits for dollars spent. In the allocation of these resources among research, disease prevention, and the delivery of health services, there must be recognition of the interests of all the consumers involved, including health professionals, institutional providers, and health related industries.

Because of the nature of biomedical research and the difficulty of carrying out valid cost-effectiveness analysis of health practices, it is hard to provide "decision makers" with quantitative data on the precise degree to which biomedical research affects the quality and cost of today's health care. Those responsible for policies in this area must work with this reality. To approach the problem of containing health care costs by placing inappropriate or ill-conceived constraints on the generation of new knowledge may undermine our best chance to develop the very technology that will both improve quality and be cost-effective.

In this paper, I will comment on two related issues. First is the long-term objective of biomedical research, namely, the development of technological measures that will prevent or definitely cure disease and will constitute the most cost-beneficial approaches to health care. To realize this objective, with our present intellectual opportunities and economic constraints, we need a federal policy of relatively stable, programmatic support at a reasonable financial level. Second is the need to develop an effective monitoring program to examine the application of any new technology in our health services "system," once efficacy and safety (at least on the relatively limited short-term basis) have been established. Such a program should provide data on costs and benefits of medical technologies being used in clinical practice settings. This will require a close partnership between the public and private sectors of the health care system. It will also require the establishment of a federal office charged with the coördination and operation of the program, including assembling, evaluating and disseminating analyses of the need for the new technology and the appropriateness of its applications.

Scientific process

To consider the role of biomedical research in health policies related to quality and cost issues, we must understand the scientific process.

There is a growing public impatience with the failure of research to provide cures for diseases still rampant in our population, from alcoholism and drug abuse to heart disease and cancer. Is there any sort of regular, predictable pattern discernible in highly successful biomedical research that might be codified and duplicated to speed up the process in areas still unresolved? However much we would like a positive answer, the pattern remains obscure.[1] All that one can conclude with certainty is that progress in biomedical research requires more time than one generally anticipates, hard work, and, above all, very bright, dedicated, and imaginative scientists and physicians. But most applied research is likely to succeed only when there is an adequate scientific base from which to attack the targeted problem. The essence of the scientific process is that it is a stepwise extension of what came before. What seems to be a "breakthrough" almost always proves on close examination to be a discovery based on established scientific facts accumulated over a period of time. One of the outstanding examples of the contribution of biomedical research to health care, the use of antibiotics for the treatment of infections, dates back to the late 19th century, when Koch established the fact that specific bacteria cause specific diseases. Thus, there is an imperative need for continuity in the programming and funding of biomedical research.

Support for biomedical research

A commitment to public support of biomedical research was made a quarter of a century ago, with the creation of the expanding programs of the National Institutes of Health (NIH). This commitment, however, has been in the nature of short-term, renewable agreements, in the sense that programs can be reduced one year and increased the next. This has probably led to inefficiencies in the research enterprise and increased the cost of publicly supported biomedical research. Perhaps the most important aspect of federal support of biomedical research that should now be assured is a stable level of funding for the scientific enterprise that incorporates sufficient flexibility to take advantage of new opportunities.

Technology in health care and its effects on costs

New health care technology has been cited as a factor contributing to the increase in medical care costs. Indeed, it has even been suggested that controls on our knowledge production should be imposed to achieve cost containment in health practices.[2] The increasing use of this technology in medicine has been singled out by several policy analysts as a key factor in the cost increase problem.[3, 4] However, the opposite conclusion has been reported from the Public Services Laboratory at Georgetown University.[5] Mushkin et al. found that "health research, according to the preliminary findings, on balance accounted for only about 4 percent of the total increase in health expenditures during the period of 1963 to 1977. Health expenditures during this period increased on an average of 11 percent per year." Of the 11 percent annual growth rate, price increases accounted for over 50 percent, 10 percent was accounted for by population growth, and over 30 percent was attributable to the rise in demand. The residual, which may be attributed to technology, accounted for less than 4 percent of the total increase over the period. These analysts suggest that "technology, on balance, had little net impact on health outlays."

On balance, there may have been cost savings. For some illnesses, new technologies, such as new forms of chemotherapy, have become available where none existed, and this has increased the cost of health care. But for others, such as infective and parasitic diseases, new procedures for prevention and treatment have reduced the cost of health care. Admittedly, the data needed to make valid estimates of the cost-effectiveness of new health technologies are generally lacking.

It is encouraging that there is an increasing effort to develop valid approaches to cost-effectiveness analysis of health practices.[6,7] These theoretical and empirical efforts must continue. However, as a recent Institute of Medicine (IOM) report states,[8] "Until better data are available, all attempts to recommend and implement policies as to the use of new technologies must and will be viewed as tentative . . . ." It is likely that a more cost-effective return from our biomedical research will be realized as we develop better mechanisms to assure that those new methods of prevention, diagnosis, and therapy which are applied widely through the health care system are effective and efficient.

Biomedical research and technology development and transfer

The process from the discovery of new knowledge to its health care application represents a continuum. In reality, however, progress from basic research to application in clinical practice rarely, if ever, proceeds in one directional only. There are almost always many tangential observations, false starts, unexpected developments, and returns from clinic to laboratory. For organizational purposes, the continuum may nevertheless be arbitrarily considered to involve six steps:[1]

1. Discovery through research of new knowledge, and relation of the new knowledge to an existing base.
2. Translation of new knowledge, through applied research, into new technology.
3. Validation of the efficacy and safety of new technology through clinical trials.
4. Dissemination of new technology into health practice, together ideally with assessment of the new technology to obtain the data necessary for estimates of its cost-effectiveness.
5. Education of the professional community in the proper use of the new technology.
6. Education of the consumer as to the nature of the development.

A number of public agencies, private institutions, and health related industries are involved in one or more of these steps. The NIH, among federal agencies, has a primary role in steps 1, 2, and 3, and to some extent 4, that is, discovery of knowledge and translation of new knowledge into new health procedures, as well as validation of such procedures in clinical trials. Steps 4, 5, and 6, dissemination of the new technology and professional and consumer education, are not primarily in the realm of basic or clinical biomedical research and have been largely beyond what is considered the primary mission of the NIH. However, other federal agencies are involved in technology decisions at these levels, among them the Social Security Administration, through Medicare, with its responsibilities for reimbursement policy. That agency's decisions, however, are based on what is generally accepted as reasonable and necessary practice. In instances of new technology, Medicare may seek advice as to safety and efficacy from the Bureau of Quality Assurance of the Health Services Administration or the Food and Drug Administration (FDA). Cost-effectiveness is generally not a factor in determining reimbursement. Professional Standards Review Organizations (PSROs) are responsible for assuring that services provided are necessary and meet appropriate professional standards; they have no capability for technology assessment or cost-effectiveness studies. Other agencies that affect the transfer of technology are the federal Center for Disease Control, the National Institute of Occupational Safety and Health, and the Health Services Administration, as well as regulatory agencies at the state and local levels, individual and institutional providers, health related industries, and health care reimbursement agencies.

The fact remains, however, that a serious weakness in American health policies lies in the interface between health research and health care. Existing procedures are inadequate to discourage the inappropriate use of costly technologies (i.e., CAT scan), while other technologies are unevenly available to the consumer (i.e., proper use of antibiotics). The CAT scan, as a case in point, appears efficacious and, if properly utilized, can have a positive impact on reducing health care costs. This new technology appears to be an important advance. In this instance it is not the technology per se that may increase health care costs, but its inappropriate use.

As pointed out in a recent Institute of Medicine report,[8] "Well designed studies of the efficacy of procedures are necessary to evaluate any technology, but the completion of studies prior to the introduction of new technologies is very unusual. At present, such studies are not required or coordinated by any organization, public or private, and no system exists to identify areas for evaluation of emerging technologies at an early state."

A recommendation

There is need for a policy to deal with the problem of evaluating the relative benefit and cost effectiveness of any new technology.[9] The goal is to assure that only appropriate, necessary, and cost-effective technology be transferred to health practice. It is also necessary to determine the economic and social impact on health care of the dissemination of technologies whose efficacy and safety have been established through clinical research, including clinical trials.

A number of elements must be assembled to accomplish this complex task. These include, but may not be limited to, scientific expertise to determine which technologies are suitable for dissemination into health practices, and economic, social, and epidemiological expertise to evaluate the impact of technologies on health practices. (The participation of experts in these fields has been difficult to achieve in the traditional disciplinary institutes of the NIH, as it has been in traditional departments of basic science or clinical disciplines in our medical schools and academic health centers.) In addition, health related industries, health care providers, reimbursement agencies, and informed consumers are and must be involved in the appropriate development and application of technology.

It is therefore recommended that a federal office be created to coordinate the introduction of new methods and the evaluation of established techniques for prevention, diagnosis, or therapy of disease. Such a federal agency would be responsible for assembling, analyzing, evaluating, and disseminating information with respect to the need for medical technologies and their utilization and costs in the health system. The office should turn to NIH for the science evaluation and clinical trials (i.e., for data and judgments as to efficacy and safety). A means would also be needed to evaluate the impact of a technologic innovation on consumer health status, health professionals, facility resources, and costs. Since at present the capacity to do so is largely outside the realm of expertise of NIH, one could consider establishing it there. Alternatively, the responsibility could be assigned to an agency more directly involved in health services. The latter approach is preferable, primarily because such evaluation should proceed in a health care delivery setting.

To be effective, the coordinating agency would need to be able to monitor the dissemination of technology. It is difficult, however, to control the dissemination of new technology and at the same time to maintain the incentive necessary to assure continued innovation in the private and public sectors. One might consider establishing a network of centers, perhaps consisting largely of existing academic health centers, which would be recognized as the primary setting for the evaluation of such new technologies and their dissemination into the health care system. A model for this approach could have some of the elements of the National Cancer Institute program of designating cancer centers for evaluating certain new technologies.

In order to influence the health system to move toward widespread introduction of only necessary and cost-effective technologies, this new approach will rely heavily on dissemination of appropriate information as to the benefits, hazards, and costs of a new technology. The approach may be given considerably more leverage if that information is used as a basis for establishing guidelines for reimbursement for particular services to institutional and individual health care providers.

It is necessary to consider the cost of this proposed evaluation program. Since the dissemination of a new technology is largely a health service matter, the cost of the program should be reimbursed like other health service costs. There would be related incremental costs, which should include only those related to collection, evaluation, and dissemination of data and collateral information. It would be unfortunate, however, if the present constrained budget for the support of biomedical and clinical research were reduced to provide funds for improved technology transfer. This would undermine our ability to develop the new technologies that are most likely to achieve the decisive and effective measures we seek for the prevention and/or cure of diseases.

The essential step in this proposed program is to develop a process to obtain the necessary data for appropriate decisions as to whether initially new, but eventually established and widely used preventive, diagnostic, or therapeutic measures should be generally available in our health care system. Still, it is likely that such data will frequently lead to ambiguous conclusions. Our procedures for evaluating the impact of new technology on health practice are still relatively crude. Technology development itself is, and must continue to be, a dynamic process. Nevertheless, better judgments are likely to be made if we have better data. The goal should be continued innovation, with the intent that only medically necessary and appropriate use of technology occur. It is unlikely that this goal will be achieved to everyone's satisfaction, but we can do better than we are doing now. A critical aspect of the proposed program is that consumers must be involved in the decisions and recognize that biomedical science is capable of developing technologies that are useful but too expensive. Even with good data on benefit and cost effectiveness, decisions to withdraw, withhold, or not avail ourselves of a technology may be difficult. The process should be oriented toward developing informed professionals and consumers rather than toward regulatory actions to constrain the use of new technologies. We cannot expect this approach to be without problems or pitfalls. This is a difficult task. What we can expect, and must begin to realize, is a focus for leadership to address this problem.

In summary, the time is appropriate to urge the Congress and the Executive Branch to charge a federal office, perhaps within HEW, with the overall responsibility for developing and implementing the processes required to assure the appropriate and necessary transfer of technology into the health care system. Careful study is urgently needed to provide a basis for determining where and how the responsibility for this mission should be assigned. As noted above, even out of justifiable concern for the rising costs of health care, moving inappropriately to control our knowledge production as a means of achieving cost containment in the health care system could have unfortunate results, both for the future health of our people and for the hope of future cost containment through prevention and cure. Efforts to improve the articulation between knowledge development and knowledge application in health care will be made more effective if a focus for leadership in directing, coordinating, and evaluating these efforts is established.

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Controlling health technology

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Introduction

In recent years, the issue of medical technology and its relation to costs has occupied a prominent position on the health care agenda. Evidence of this heightened interest comes from many sectors. In 1975, in testimony before the President's Biomedical Research Panel, the Social Security Administration pointed out the budgetary impact of technological innovations.[1] In 1976, a conference on health care technology at Boston University grappled with the problem of escalating costs and discussed various policy options. In the Congress, the Office of Technology Assessment was established to assess the physical, biological, economic, social, and political impacts of technological changes in a variety of substantive areas, including health. Despite this attention, no concrete action has been taken to deal with technology induced inflation, nor, for that matter, has there even been agreement on how to deal with it. This paper defines the nature and extent of the effect of technology on health care costs, and focuses on five major approaches to controlling it. The causes of the technology explosion in the health industry will not be discussed, as they have been covered elsewhere in the proceedings (in Schroeder and Showstack).

The problem

The health care industry differs from other industries in that it does not respond to standard economic theory. The laws of supply and demand do not apply; the consumer has little influence on the market; competition is a negligible factor, etc. And while in most industries new technology is often added to decrease costs and improve productivity, technological innovations in health care do not appear to have the same effect. On the contrary, they tend to require additional personnel, greater skills, and more tests and equipment, thus giving rise to higher costs. Although in most industries the technology problem is one of not getting innovations into the market rapidly enough, in health care there is concern that diffusion is too rapid.

The rapid diffusion of innovative technologies has brought mixed results. In some cases, it has saved lives or reduced disability; in others it has had negative effects; and in still others the results are unknown. However, in all cases, excluding drugs and recently developed medical devices, medical technologies have not been subjected to rigorous testing before their introduction. Rather, first, they are diffused and employed, and then, if after many years they are found to be unsound or obsolete, they may be removed. Computed tomography (CT) body scanners are one example. No doubt their effectiveness, costs, and humaneness are unexcelled in some clinical cases. However, as a routine and frequently used diagnostic test, their effectiveness has not been determined, nor is there any professional consensus that they are useful. Nevertheless, they are being purchased in substantial numbers. The United Kingdom has a total of only eight CT body scanners for a population of 50 million—one per six million persons. But one four-county area in California has five for a population of 600,000—one per 120,000 persons. Another example is the case of treating breast cancer with radical mastectomies, a heretofore conventional treatment but one whose effectiveness has only now begun to be assessed. Preliminary results indicate that in certain cases simple mastectomies may be just as beneficial.[2] In addition to the immense psychological benefits of the simple procedure, the surgical fees are almost half. We have been paying twice as much for one procedure as compared to another, but we never bothered to test whether or not it was better. In another example, we recently learned that mammography, introduced several years ago, may, for women under age 50, cause more deaths than it saves.[3] Even procedures known to be beneficial are often misused or used too much. Tonsillectomy rates are eight times as high in one community as in another; the rate of hysterectomies has increased 30 percent in the last ten years; and hospital stays are three times longer in one part of the country than another for the same conditions. Such widely used technologies as chemotherapy, open-heart surgery, and organ transplant are still being questioned regarding their appropriate use.

Some means are needed to prevent untested technologies from entering the market without preventing beneficial technologies from entering soon enough. We need to determine when to use our technologies and find ways to restrict their use to those circumstances. And even if a technology results in improved health status, is the improvement worth the costs? Besides failing to evaluate effectiveness in terms of change in health status, we rarely weigh the costs of technologies against their benefits. Even the Food and Drug Administration (FDA) is not required to consider cost-effectiveness in approving new drugs and devices. When Medicare determines whether or not to reimburse a new procedure, cost-effectiveness is not considered. One researcher estimates that we are now putting tens of thousands of people in the hospital each year at a cost of $43 million to save each additional life.[4] The issue is not necessarily whether each life is worth $43 million, but whether many more lives could be saved for the same $43 million used more wisely.

The extent of the problem

It is not simple to measure the amount and direction of technology's impact on health costs. First, the definition of "technology costs" can significantly affect the results. For example, is the cost of technological change measured in terms of the cost of changes in a specific treatment, or does it include changes in the utilization of the treatment as well? Does it represent the cost of a particular piece of equipment or does it also include personnel cost? Second, once a definition is formulated, it is even more difficult to measure the total health care system effects of technology. Technology-induced increases in hospital costs, for example, may result in decreases in ambulatory care costs. A costly preventive measure may result in avoidance of a disease which is even more costly. These total system effects have never been fully examined, partly because of methodological difficulties and partly due to a lack of appropriate data. Both Mushkin[5] and Fuchs[6] measured the effects of all the variables considered to contribute to the increases in total health expenditures and defined the residual as the effect of technology. Their results were contradictory.

Most of the analyses of the cost impact of technology have concentrated on hospital costs, the largest area of health spending. Feldstein,[7] Davis and Foster,[8] and Waldman[9] attempted to eliminate the effects of inflation and rises in wages on the increase in daily hospital costs and attributed the remainder to technology. Although they used somewhat different methods, all reached the same conclusion: real inputs, i.e., care intensity, accounted for nearly half the rise in per diem costs in the late 1960s and early 1970s. Waldman's method, applied to rises in community hospital expenses over the last decade, shows intensity accounting for 45 percent, indicating that we spent over $10 billion in 1976 to provide a higher level of care than we had in 1966. Klarman made adjustments to the Waldman technique which reduced the intensity impact to 33 percent.[10]

In another study, Redisch indicated that the growth of seven medical services alone (pathology tests, nuclear medicine procedures, pharmacy items, laboratory tests, diagnostic radiology procedures, laboratory radiology procedures, and blood bank units) caused one-third of the cost increase per adjusted patient day between 1968 and 1972.[11] Finally, Worthington found that between 1950 and 1973 changes in real nonlabor inputs accounted for 77 percent of the variation in the change in annual per capita expenditures for hospital care.[12] Although nonlabor inputs include more than technology, technology is undoubtedly an important factor.

In recent years, the contribution of new technologies to increases in hospital costs has probably diminished. The American Hospital Association claims that pure factor price increases accounted for over 70 percent of hospital cost advances between January 1974 and June 1975. Application of the Waldman method for the 1974–1976 period shows that the share attributable to intensity decreased to 38 percent of the increase in adjusted daily hospital costs. This decline in the intensity factor may be due to expanded minimum wage laws and collective bargaining, higher costs for energy and food, and much higher premiums for malpractice insurance.

Altman and Wallack evaluated the various attempts to measure the impact of technology and concluded that "resource-intensive advances appear both to have raised the per unit costs of treatment and to have led to the use of more of the most expensive types of treatment."[13] This conclusion was debated extensively at the conference and the consensus, as reflected in the *Report of Symposium*, was that "incremental hospital care cost attributable to technology over the past decade is believed to be in the range of 20 to 40 percent."[14]

Methods of technology control

Paramount to controlling medical technology is the need to evaluate its efficacy and cost-effectiveness. Present federal expenditures for such evaluations amount to less than $.5 billion annually—not nearly enough to cover the cost of conducting even a small proportion of the needed evaluations.

In another paper, we proposed the establishment of a Technology Evaluation Administration to collect and disseminate scientific data on the efficacy and cost benefit of medical technology.[15] We suggested that such an agency be responsible for synthesizing what is known about the efficacy and cost-effectiveness of current technologies; generate assessment of those practiced technologies not yet evaluated; provide assessment of new technologies not yet diffused; and appraise the potential impact of new technologies prior to their development.

Whether such an agency is developed or an alternative approach pursued, some evaluation mechanism must be established for technology control to be meaningful. We know that technological innovation is expensive, but we do not know what we are getting for our money. Technological development should not be curtailed, nor should there be arbitrary decisions about which technologies to embrace and which to eliminate. But each technology must be evaluated scientifically to weed out the ineffective ones and retain those that are efficacious and cost-effective.

There are five approaches to technology control suggested here: planning controls, reimbursement limits, direct market entry regulation (FDA model), physician training, and consumer education. These approaches can be used singly or in various combinations.

Planning controls

Capital expenditure limits. A national limit could be set on these capital expenditures controlled through the Certificate-of-Need (CON) program. These expenditure limits would then be allocated by State and/or Health Systems Agencies. This measure is similar to Title II of the Administration's Hospital Cost Containment Bill (H.R. 6575), which places a $2.5 billion national limit on capital expenditures.

A capital limitation puts clout into the Certificate-of-Need legislation. Certificate-of-Need agencies have been approving over 90 percent of the applications they receive, partly because they have had very little incentive to counter the pressure from hospitals, physicians, and consumers to spend more, particularly since much of the money to pay for such equipment or buildings comes from the community. For such a spending limit to be fully effective, however, more definitive standards and guidelines would have to be developed to govern the allocation of approved spending. The Lewin study on the effectiveness of Section 1122 controls found that few agencies can conduct review functions effectively because of inadequate need projections, review criteria, or data resources.[16] Without definitive allocation standards, two neighboring hospitals could be granted approval to equip open-heart surgery units, while an application for needed modernization elsewhere was rejected. Under the proposed schema, spending would be limited, but, it is to be hoped, wiser.

Expansion of Certificate-of-Need authority. CON authority could be expanded to include physicians' offices and clinics and to require recertification of facilities. Unless physicians are included under CON, they are likely to purchase additional equipment and run additional tests in their offices when "rent-free" workshops become less accessible to them inside the hospital. This reaction is already becoming evident. About one-sixth of the scanners in use are located in private offices or clinics, and threats of private purchases are made now when CON agencies turn down requests from hospitals for such equipment. Further, insurance coverage is generally better for diagnostic tests than for other procedures in the physician's office. With the growing threat of malpractice suits, it is easy to imagine a future plethora of diagnostic equipment being purchased for use in physicians' offices.

Expanding CON authority to include recertification could also ameliorate current maldistribution of capital. In the early 1960s, the President's Commission on Heart Disease, Cancer, and Stroke estimated that 30 percent of all hospitals equipped to do closed-heart surgery performed no operations in the study year. Of those equipped for open-heart surgery, 44 percent averaged less than one operation per month and over three-fourths averaged less than one per week. Mortality rates from these procedures were inversely related to the frequency with which they were performed at an institution. Requiring recertification of facilities and equipment could reduce unused capacity; for example, excess scanners in one area could be moved to another. Further, expanding CON to include recertification could eliminate many unstarted projects currently approved as a result of grandfathering. It is estimated that California alone has over $3 billion in capital projects approved through grandfathering but not started.

Restricting capital financing. Federal revenues and tax-exempt bonds are the major sources of funds that finance hospital construction. About one-fourth of the funding involves the federal government through grants, Hill-Burton loans, guarantees, interest subsidies, and HUD loan guarantees. Tax-exempt bonds provide another one-third of the funds.[17] Although financing for construction does not usually involve individual equipment purchases, the availability of these sources frees other capital funds for such purposes. Further, much of hospital construction today involves modernization, which includes adding facilities such as burn units and cardiac intensive care units — all technology related.

Stricter criteria could be developed for federal participation in capital financing from private sources and tax-exempt bonds. In addition to requiring Certificate-of-Need approval, the criteria could include maximum limits on operating costs resulting from the project, measures of availability of alternative facilities in the area, and special consideration for cost-saving institutional mergers.

Reimbursement limits

Caps on hospital revenue increases. Applying a limit to the increase in reimbursement from all payers would force hospitals to exercise caution in expanding the number of tests they performed, equipment they purchased, and personnel they hired. Because they would not be paid for every new service they provided, more conscious decisions would be made on how to allocate their potential revenues. As all hospitals would be operating under the same constraints, the revenue limit approach would help to moderate the negative competitive elements among hospitals.

But there are some potential problems with this approach. Hospitals could limit the wrong — from the viewpoint of the patient — technology. The method could penalize hospitals that had exercised caution in the past and now would have to "compete" with neighboring hospitals that had been less restrained. Further, employing this approach without some complementary method of dealing with physicians fails to recognize the major role that physicians play in technology inflation and the fact that physicians can easily move their "workshops" to their offices.

Ideally, in the future, prospective reimbursement rates could be established that reflected an efficient level of operation for each hospital and included an increase factor for the adoption of approved technology.

Procedure reimbursement limitation. This approach requires developing a protocol for reimbursable technologies that is based on proven efficacy and cost-effectiveness. Such a protocol would deny reimbursement to those technologies proven totally ineffective and limit payment for others to appropriate use. The list could include drugs and equipment, as well as procedures. For example, influenza vaccinations have been found to be efficacious and cost-effective only when given to the aged and persons with certain conditions. Thus, reimbursement of flu shots would be approved only for those persons.

Most third-party payers currently maintain a list of reimbursable procedures that are performed both in and out of the hospital. However, most of these payment schedules, like those for Medicare, restrict reimbursement to procedures that are reasonable or necessary, where "reasonable" or "necessary" are basically defined as "generally accepted." Neither efficacy nor cost-effectiveness is considered. Even in the case of new procedures, where efficacy is taken into account, cost-effectiveness is not.

Some of the private insurers are changing their procedure list to allow payment for appropriate use only. On May 18, 1977, the National Association of Blue Shield Plans announced that it will end routine payment for 28 medical procedures considered unnecessary under certain circumstances. These procedures — 18 surgical and 10 diagnostic — include specified instances of radical hemorrhoidectomy, hysterectomy, sympathectomy, basal metabolic rate testing, and angiography. Written justification for use will have to be made by the physician before payment is authorized, with local physician review panels settling any resulting disputes. Although the Blue Shield approach does not include development of protocols for appropriate use, it does make physicians aware that certain procedures have questionable usage; it makes them consider the costs of the procedures they order; and it makes them more cautious about ordering them, since reimbursement is not guaranteed.

Adoption of a protocol development approach to procedure reimbursement could affect all health technology use, regardless of site of care, and could permit the current reimbursement system to operate otherwise unchanged. It would have a natural inhibiting effect on unnecessary demand. Demand for scanning, for example, would decrease if reimbursement were not always available; purchase orders for scanning equipment would diminish as a result. Also, the physician's role in malpractice suits would be greatly clarified and protected. If private health plans could work collaboratively with the government, their lists would be compatible and the costs associated with producing the lists could be shared. Their efforts could be enhanced by modification of the Professional Standards Review Organization program, which now reviews "necessity" for the federal financing programs. Thus, HEW would be responsible for developing national protocols, while local PSROs would monitor compliance and apply reimbursement sanctions and other penalties.

The disadvantages of the approach are that development of protocols would be extremely expensive and require long implementation time; reimbursement procedures might require more data and more paperwork; and perfect "protocols" could probably never be developed to handle every circumstance, so that flexible application would be needed.

Technology-sensitive fee schedules. This alternative would establish national reimbursable fee schedules, with a pricing system for physicians' services adjusted to make it less profitable for them to use expensive, marginal technology. Thus, technology adoption might be slowed and deployed only where absolutely medically indicated. As new procedures and equipment were proven cost-effective, the fees could be increased. Initially, reimbursement rates would be set so that no increase in physician net income could result from unproven technology. The ultimate decision for technology use would rest with physicians on a case-by-case basis, but the "profiteering" from hospital-purchased equipment would be eliminated. Because third parties pay only 61 percent of expenditures for physicians' services, the impact of this approach might be limited until broader national health insurance coverage is enacted.

Direct market entry regulation (FDA model)

This approach would require all technology — procedures as well as drugs and medical equipment — to undergo federal examination and approval before utilization would be legal. Currently, for drugs and devices to receive FDA approval, the manufacturers must prove that their products do not cause harm and represent improvements over existing ones. Although cost-effectiveness is currently not required, it should be in the case of technologies. In addition, use of unapproved technology would be restricted to experiments and clinical trials.

Although this method of curbing technology-induced inflation might delay or prevent the adoption of many innovations, it would not curb the use of technology once it was permitted to enter the marketplace. It could be effective, however, in preventing the diffusion of useless or harmful technologies and would have the potential of providing a rich data base on risks and benefits. But it would be expensive to implement. Further, if it were applied to existing technologies it would be difficult to implement and could forestall use of a potential major breakthrough until the required years of testing were over.

Physician training

Reducing specialization. There is a growing evidence that the specialists are the technology abusers. Feldstein estimates that the addition of one or more specialists caused hospital costs to increase by $39,000 per year between 1958 and 1967.[7] The addition of a general practitioner, conversely, led to hospital cost decreases by the same amount.[7] Worthington found that most of the real inputs employed across all physician practices could be attributable to increasing specialization.[12]

The Health Professions Educational Assistance Act of 1976 (P.L. 94–484) calls for a decline in the ratio of specialists by 1985. The need for a greater proportion of primary care physicians has been argued elsewhere for overall health reasons, but technology abuse would decline as well. However, this approach would take years to achieve cost savings and would do nothing to curb the current abusers.

Physician education. The current training of new physicians heavily emphasizes the use of the latest procedures and equipment. Even persons being trained as primary care physicians attend the same medical schools as the future specialists, institutions where "modern medicine" is epitomized by the best-equipped, around-the-clock diagnostic and treatment facilities. A return to teaching "black bag" medicine might go far in reducing future dependence on the "best" and the "most."

Sending physicians copies of their patients' hospital bills might also make them more aware of the financial impact of what they do and what they order. Their fee for a surgical procedure may be only a few hundred dollars, but such an operation will generate many additional costs, i.e., the cost of the operating room, preoperation work-ups, and postoperative care. Together these added costs run into thousands of dollars.

Finally, should data become available, physicians also could be armed with statistics on the odds of success under various circumstances, the risks with and without a procedure, and the costs to the patient and society in terms of dollars and discomfort.

Consumer education

Under this approach, consumers would be educated about the costs of the medical care they receive. As they do not always receive a hospital bill, they often have no idea what their stays have cost, or even what services and supplies were furnished. If patients received copies of their bills, they would become more aware of the cost of the services they demand and would perhaps question their necessity.

Since consumers usually pay just a share and sometimes none of the costs of insurance, they do not feel the effects of rapidly rising premiums. Employers and unions who do could inform workers of premium increases and what they mean in terms of reduced wage hikes. If the impact of premium increases on their pocketbooks were brought home to them, consumers might question the use of "marginal" services.

The media could also be used more to publicize the need for second opinions in surgery, the existence of unnecessary operations and tests, and the uncertainty surrounding medical practice. Health care is the one consumer good where informed choice in buying is not involved. The consumer "buys" what the "seller" tells him to. He has little basis on which to choose not to buy, to bargain, or to take his business elsewhere. Doctors are usually perceived as superhuman. If the patient were enlightened about some of the uncertainties, the costs, and the risks, some of this behavior might be modified. For example, with the development in recent years of extraordinary measures to prolong life for a limited time, patients have become aware of the "death with dignity" issue. They have begun to express concerns about vegetating, or being subjected to numerous and painful procedures that have little chance of significantly altering their outcome. As a result, they have started to bring pressure for legalization of "living wills" to prevent usage of these extraordinary technologies in hopeless cases. Further publicity and exposure through the media of the "living will" concept may result in additional pressure and additional legalization. As a result, costs will be saved and, at the same time, the patient's desires will be met.

Summary

Much uncertainty surrounds innovative medical technology. Questions such as when certain technologies are appropriate, how much good they do, and what their costs are remain unanswered. In this era of conflicting needs — balancing the federal budget, yet solving our social problems — we cannot afford the high costs of goods and services about which we know so little.

Five approaches to technology control have been suggested: planning controls, reimbursement limits, direct market regulation, physician education, and consumer education. Whether one or a combination of these approaches is adopted, none will be effective unless a data base is developed which can tell us which technologies to use and when.

The "technology problem" is not simply one of cost restraint. It is also a problem of learning how to improve our health status by optimizing technology. Until we learn what works and what does not, the costs, the risks, and the benefits, we cannot make informed decisions on the best use of our limited resources.

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Regulating the cost of health care: A discussion and a proposal

Richard A. Berman and Thomas W. Moloney

A major theme of this symposium is the potential effects of invoking regulatory authority to limit the diffusion of new medical technologies, with the aim of slowing the overall rate of increase in health expenditures. Two very different views of the merits of this idea have been presented by Alain Enthoven and Roger Noll, and by Clifton R. Gaus and Barbara S. Cooper. Enthoven and Noll find little reason to think any regulatory intervention will work: "Attempts to control prices, capacity, and the quality of service by direct intervention are more likely to exacerbate problems in these areas than to ameliorate them." Gaus and Cooper, on the other hand, think regulatory intervention will work, and discuss five different regulatory approaches to control "technology explosion." Two responses, so wide apart, suggest that some interpretation and counterpoints may be useful, as each response raises important issues needing further exploration. For example, despite a traditionally sharp set of scholastic arguments as to why regulation cannot work,[1 2 3] health care regulation in this country is continuously increasing and broadening: we will challenge certain observations in the Enthoven/Noll paper to see why this is the case. New forms of regulation bring the possibility of new sets of undesirable practical consequences: we will explore the consequences of options presented in the Gaus/Cooper paper to avoid the possible damaging side effects of various interventions.

We will also explore an alternative: a strategy for bringing the rate of increase in health care expenditures in line with the overall rate of growth in the economy, a strategy that leaves hospitals and planning agencies the maximum authority possible in making allocation decisions, but which offers considerable help with the complex issue of developing area-wide guidelines for distributing medical care resources.

Can regulation work?

Enthoven and Noll describe three generic types of policy response to the problem of rising health expenditures. Only one, they believe, is feasible. It entails a restructuring of the delivery and financing system in order to alter the basic financial incentives facing providers. The basis of their recommended approach is new developmental incentives for HMOs: "A fair market test for HMOs is hardly a new idea, but it still has not been seriously tried." A number of policy makers agree that a fair market test of HMOs is a good suggestion.[45] The limitation of such a test is that it is not likely to reduce overall health expenditures substantially within the next decade. The authors themselves observe that "physicians and consumers are accustomed to the fee-for-service, third-party intermediary system and would reject an attempt to change it suddenly and drastically." To many observers, a decade is simply too long to wait. Both interest in enacting some form of national health insurance and other competing domestic priorities have made concern for expenditure control more immediate.[46] A fair market test of HMOs should proceed, but, we will argue, along with other interventions aimed at speedier results.

A second option discussed by Enthoven and Noll is to increase the extent of consumer cost sharing greatly so that patients will have much more incentive to economize on medical services. However, they reject this option. They find it contrary to private insurance objectives and to public policy on access to medical care. The purpose of private insurance is to prevent serious financial loss; a large increase in deductibles and coinsurance would increase the risk that a person suffer serious financial loss in the event of a major illness. Government medical care programs aim not only to reduce the financial risk for its citizens but also to provide them with access to needed care; deductibles and coinsurance, in effect, would reduce that access. These objections are straightforward and voiced by other observers as well.[7]

A third option, the authors recognize, is to impose economic and technical regulation in order to limit the diffusion of new medical technologies. The merits of this option, as we have said, are a major theme of the symposium. Enthoven and Noll reject it on two bases: on a theoretical-historical analysis of the general behavior of regulating agencies in other industries, and on an interpretation of the evidence of past failures of regulatory agencies to limit the growth of hospital capacity.

The theoretical-historical analysis contends that because medical care is provided by numerous independent actors, and because it is difficult to define and measure the products of medical care, regulatory intervention has to proceed on a case-by-case basis, "with all the costs and deflection of policy that the case approach necessarily entails." What seems necessarily entailed is twofold. First, there is a protective attitude on the part of the regulating agencies toward regulated firms that renders regulation ineffective: "When regulation is complicated by sophisticated data requirements, heterogeneous firms and vague objectives, regulators are especially prone to be protective of regulated entities that are on the verge of financial failure." Second, this behavior by regulatory agencies can become reinforced because politicians too become protective of regulated entities: "An agency may be punished by Congress or the Executive Branch if it forces a truly inefficient operation into bankruptcy whenever the rectitude of its position is less than certain. However, it faces no concomitant penalty if it offers protection to the failing enterprise."

When these two conditions actually occur, they set up what has been characterized by political scientists as an "iron triangle" formed by the Congress, the regulatory agency, and the regulated industry. The basis of the "iron triangle" theory is that regulatory agencies don't control the industry firms; on the contrary, the firms control the agencies. Therefore, the agencies don't serve the public interest, but promote special interests at the expense of the public. Though there is general agreement among many social scientists that this takes place, they differ in their interpretation as to why and how.[8] Samuel Huntington suggests that there occurs an out-and-out political capture of an agency by its regulated industry. Marver Bernstein suggests that agencies begin by advancing the public interest, but, through a natural evolutionary process, slowly lose their sense of mission and eventually lapse into serving special interests. Others, like Gabriel Kolko and George Stigler, argue that regulatory agencies have not lapsed from their initial mission; rather, they always intended to serve special interests.

But these may be the explanations of a bygone era, for today there is evidence that the "iron triangle" theory is descriptive only of those agencies founded between 1887 and the outbreak of World War II. It is the old agencies that were cartel-like in structure and effect — and more often mandated to protect than to regulate. They were based on statutes that conferred extremely broad powers on them and provided little specific policy guidance. In former days, regulator and regulated often existed in a comfortable, cooperative relationship, one in which the agencies felt responsible for the economic well-being of the industry they had jurisdiction over.

This is quite a different description from what Paul Weaver finds to be true of the newer regulatory agencies.[8] Typically, the laws establishing the post-World War II agencies are extraordinarily lengthy and specific. The agencies are established to operate as the adversaries of the interests they regulate, and typically it is as adversaries that they administer the law. In some cases, they are explicitly forbidden to be concerned about the cost of their pursuit. For example, the Occupational Safety and Health Administration (OSHA) may not take account of the cost of health regulations except in the extreme case that it might push a company into bankruptcy. There is a "new triangle," composed of public interest groups, the press, and the federal government as a whole, says Weaver. It is motivated by concerns for health, safety, and the environment and a "passionate sense of opposition to members of the old iron triangle."

He concludes:

> Even as a description, the literature on regulation is getting to be very misleading. Over the past decade, the federal regulatory establishment has been greatly expanded by a long series of new laws in the areas of health, safety, and environment. For a variety of reasons — not the least of which is that legislators or their aides are aware of the social science literature — the new regulatory agencies are utterly unlike the old ones. And since the new agencies as a group now, far overshadow the old ones by any measure one might invoke — social impact, number of people employed, amount of federal money spent, etc. — the literature, merely by remaining on the library shelves, has come to convey a seriously inaccurate impression of what regulatory agencies in general are like and how they work. (Scholars are only now beginning to do serious research on the behavior of the newer agencies.)

The second component of the Enthoven/Noll conclusion that regulation is not likely to be effective is based on the authors' interpretation of regulation's record to date in the health field. They suggest that regulation of hospital capacity is a fair test of regulatory effectiveness and, when tested, is found wanting: "The available evidence indicates that Certificate-of-Need regulation has not succeeded in controlling the problem of overbedding." Their discussion suggests that data on bed capacity can be used to show that hospital capacity has not been held in check. Actually, this is inaccurate on two counts. First, our national experience with "bed capacity" since 1950 is quite different; bed capacity has been held in check, hospital capacity (total investment in plant and equipment) has not. Second, the specific periods in which strong regulatory sanctions were in effect demonstrated that overall hospital capacity could potentially be held in check.

The evidence on bed supply shows that in every five-year period since 1955, the number of total U.S. hospital beds, both federal and nonfederal, has declined per 1,000 population.[9] Different categories of nonfederal beds have increased and decreased at different rates, but the net result is a continuous decline in beds per capita for the past 20 years. The major studies of Certificate-of-Need legislation, including the one footnoted by Enthoven/Noll, conclude that in affected states the legislation did result in a lower rate of expansion in beds than in states without the regulation.[10] The difficulty with Certificate-of-Need legislation was in limiting overall capacity growth; the growth in other types of hospital investment negated the saving from the reduction in the growth of the bed supply.

With regard to the second point, our one national experience with direct regulation of overall hospital spending, the Economic Stabilization Program of 1971, demonstrated the effectiveness of strong regulatory efforts. For the first time in a quarter of a century, growth in hospital and medical care prices fell below that in the overall cost of living. For the years between the enactment of the Medicare and Medicaid programs and the beginning of the Economic Stabilization Program, the Consumer Price Index (CPI) for semi-private hospital room charges increased at an average of 15 percent per year. During the Economic Stabilization Program years, it dropped to an average of 6 percent per year. By the end of 1974, the general economy had improved and, as promised, the Economic Stabilization Program came to an end. When these regulations were removed, medical care prices moved back up to a rate one and one-half times as great as the overall CPI.[11]

There is evidence from the state as well as federal experience that overall capacity can be limited by regulatory intervention. Certain states with strong regulatory mechanisms have limited spending far better than the nation as a whole. Consider the experience of New York State.[12] In 1975 and 1976, expenses per hospital admission for the nation increased 13.6 percent, but only 4.2 percent in New York State. Acute care beds per capita increased 0.9 percent for the nation and decreased 0.9 percent in New York State (incidentally, New York State has had an 8 percent reduction in its overall bed supply in the past three years). Finally, an evaluation study funded by the Social Security Administration confirmed that during 1969–1974, New

York hospitals, while placing ceilings on the amounts of routine per diem health costs that were reimbursed, limited increases in adjusted costs per day to 13 percent. A control group of states, using conventional cost reimbursement formulas, incurred a 32.7 percent increase during the same period.

Can technology-associated costs be controlled by regulation?

From a blend of arguments, from theory and experience, Enthoven and Noll conclude that regulation of medical technologies, in particular, will not work. The overall problem in the control of technology-associated costs, as they see it, is not one of brand new equipment; rather, it is one of new combinations and more intensive use of the services already in place. This, they argue, makes effective regulation nearly impossible. How, they ask, would regulators determine what constitutes a "new" technology or procedure; what rate of diffusion of these "new" technologies should be allowed; what criteria should be used to show which technologies weren't needed? The issue of medical value is likely to be one of appropriate utilization, not one of total effectiveness or ineffectiveness. Finally, they argue, regulation will not work because it cannot effectively withhold potential lifesaving treatments: "When the issue is extra expenditures or possibly unnecessary care versus denial of access to lifesaving treatment, doubts will be resolved in favor of the former." In addition, Gaus and Cooper note that validation of cost-effectiveness, were it to be required for approval of new technologies prior to distribution, would be expensive and difficult to implement; it could in fact cause the fruits of a major breakthrough to be postponed for years. Furthermore, current econometric techniques for performing cost benefit studies of technologies may prove to be mathematically valid but irrelevant to the formulation of social policy.[13]

These concerns are formidable barriers to regulatory effectiveness only if one attempts direct regulation of the introduction and diffusion of each new technology, an option discussed by Gaus and Cooper. There is another regulatory mechanism which can be used to attain the goal of limiting technology-associated expenditures without causing these problems. That mechanism is to place an overall limit on revenue increases for hospitals and leave decisions on the allocation of resources to those responsible at each institution. This is equivalent to a different alternative presented by Gaus and Cooper: the recommendation of caps on hospital revenue increases. As the authors indicate, hospitals would be encouraged to exercise caution in expanding tests, equipment, and personnel. Because they would not be paid for every new service, each hospital would make more conscientious individual decisions on how to allocate its resources and assign priorities among alternative types of services.

Avoiding undesirable side effects of regulatory interventions

In general, regulatory strategies that establish overall limits on revenues and prices greatly reduce the number and types of problems, such as those discussed by Enthoven and Noll, which can arise when regulation is targeted at specific components of hospital services such as medical technologies. Targeted interventions present several basic difficulties, of which the Enthoven/Noll objections are a subset.

First, targeted proposals can inadvertently place regulatory approval or denial in the sphere of lifesaving equipment or procedures — a sphere where it clearly is not meant to be. With recommended overall limits instead, individual medical staffs and administrators retain authority to adopt necessary lifesaving equipment and procedures and to forego those items that provide a low marginal value. Second, targeted proposals remove the burden of responsibility for safe and effective cost control from the medical staffs and administrators at each hospital who should be responsible for directing these efforts, within overall rates of increase in expenditures. Third, targeted proposals ignore the fact that different hospitals have different needs in terms of their basic facilities, staffing, replacement of diagnostic and therapeutic equipment, and establishing wage scales equitable with those of other service industries in their area. Direct regulation, for example, of any one of these components can seriously damage the effectiveness of some hospitals while failing to cause any restraint in spending at others. Fourth, hospitals play different roles within communities in terms of the diagnostic mix of patients for whom they themselves provide service or whom they choose to refer to neighboring institutions. Targeted proposals designed to set arbitrary limits on certain components of hospital care, such as the purchase of diagnostic and therapeutic technologies, can seriously undermine the effectiveness of regional referral centers in providing for the specialized needs of an entire area. Fifth, as Gaus and Cooper point out, the development of protocols for evaluating appropriate utilization would be extremely expensive and require long implementation time. In the end, protocols to handle different circumstances adequately would probably never be developed.

If regulation through overall limits on hospital spending is to be proposed, some method must be found to distribute resources appropriately within a region. If overall limits on hospital revenues were to be applied literally, each hospital would receive the same proportional increase in overall resources regardless of its relative contribution to the health needs of people in the area in which it was located. In many cases, it would not make sense to provide each hospital with a proportionate share of new capacity. Some hospitals would be better able than others to provide highly specialized services to a large proportion of the population, to establish expanded facilities to bring new treatments to an area, and to expand their responsibility for providing services to particular subsets of the population.

However, both papers cite studies suggesting that few planning agencies can either control overall resources — that is, establish effective rationales to limit the overall number of beds, technologies, centers for special procedures, etc., within their regions — or decide how to ration these components among competing hospitals.[14 15 16] The agencies are found generally to have inadequate need projections, review criteria, and data resources.

Conclusion and recommendation

In our opinion, the rapidly rising costs in the health care sector are such that they cannot be ignored, and in fact regulatory agencies are proliferating. The question is not whether or not there will be regulation, but what kind of regulation will be most likely to succeed and least likely to cause intolerable side effects.

It seems that the best approach would be one which, within limits tied more closely to the annual rate of increase in the overall economy, left hospitals and planning agencies the maximum authority possible in making allocation decisions. It should also be an approach which recognized the complexity of making areawide allocation decisions, and offered considerable help to planning agencies by convening national scientific panels to develop areawide guidelines.

Local health systems agencies should not be expected to command the correct mix of professional expertise necessary to determine appropriate utilization standards or facilities standards for the wide variety of expensive new technologies, procedures, and other capacities which hospitals will request authorization to purchase. In order to guide local agencies in their allocation of funds, we propose that the federal government establish an operational, scientific advisory board for each new costly technology or procedure to determine the overall regional need for it and to define the types of medical institutions that could effectively support it.

These national scientific advisory boards, appointed by a federal agency, could proceed along either of two lines. If there was a sufficient existing knowledge base about an expensive new technology or procedure (i.e., any technology or procedure that would cost $250,000 or more to buy or to operate for a year), or component of health care (i.e., bed supply), the board would recommend a range of community need (i.e., one CT scanner for every million people) and the characteristics of a medical facility appropriate to house the technology (i.e., a full service hospital with 24-hour access to the technology). If there was not a sufficient existing knowledge base, the board would report the fact to the federal agency, which, in turn, would designate a limited number of sites to conduct the appropriate studies to establish a recommended level of diffusion for the particular component. Revenue increases would be granted only to reimburse for those procedures provided at sites designated by a particular planning agency. Centers designated by the federal agency as test sites for a particular research purpose would be reimbursed through specific federal appropriations.

There is a precedent for the establishment of such boards and evidence that they could work. The Committee on Controlling the Supply of Short-Term General Hospital Beds in the United States of the Institute of Medicine recommended:

> That a national health planning goal be established under the provisions of the National Health Planning and Resources Development Act of 1974 (P.L. 93-641) to achieve an overall reduction of at least 10 percent in the ratio of short-term general hospital beds to the population within the next five years and further significant reductions thereafter.[9]

The Committee on Computed Tomographic Scanning of the Institute of Medicine requested clinical trials:

> The committees' recommendations, or any recommendations affecting distribution and utilization of CT scanning, will remain deficient until better data, based on soundly conceived and executed clinical trials, are available.[17]

More specifically, the Committee recommended:

> The federal government, perhaps in cooperation with national professional and third-party payer organizations, should develop and implement a comprehensive research protocol to provide definitive evaluation of CT scanning.

The recommendations of these boards on both overall need and the types of institutions appropriate to provide new services could become major guidelines for the local health systems agencies responsible for granting a specified number of Certificates-of-Need within their regional jurisdictions. The actual selection of the institutions to receive the particular services should remain the decision of those individual planning agencies but be guided by the committees' recommendations with regard to the appropriate types of medical facilities to house the particular technologies and procedures.

This strategy would bring the rate of increase in national health care expenditures in line with the overall rate of growth in the economy. It would sidestep the side effects of targeted regulatory strategies, noted by Enthoven and Noll, and Gaus and Cooper, and discussed above. It would leave resource allocation decisions to hospitals and local planning agencies, but it would also provide them with the recommendations of national scientific advisory committees as to how to allocate these resources.

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Controlling health technology: A public policy dilemma*

Robert M. Heyssel

The focus of this conference is the cost of medical care and how and whether changes in technology exert a major influence on increases in cost. Clifton R. Gaus and Barbara S. Cooper, in their paper entitled "Controlling Health Technology,"[1] concentrate on the control of technology as a major means toward containing the cost of medical care.* Implicit in the Gaus/Cooper paper is the notion that we must curb changes in diagnosis and treatment of diseases, because medical care costs too much, and that what is called "technology-induced inflation" (a term with which, as a purist, I have a little problem as to whether it can really be called "inflation") adds almost 40 percent on an annual basis to the rising costs. Cost rises due to changes in technology are, therefore, in that construct, a major factor in the difference between the level of inflationary trends the whole economy has experienced and that experienced by the health industry.

The nature and causes of the problem of technological cost

Gaus and Cooper outline the nature and causes of the problem and suggest approaches to its solution. I do not want to spend too much time quibbling with the words, phrases, and references they cite in discussing the nature and causes of "The problem." However, there is a need to add some balance and perspective to what has been said. In places the tone of the paper is a little shrill, but it may be that this observation only reflects the ear of the hearer.

First, while one can agree that *cost reimbursement has contributed to the lack of restraint on medical care costs,* I do not believe that third-party coverage is a *cause of burgeoning technology.* While such cost reimbursement may have led to excess use of technology, it is not a cause of technology development. It has been a means of paying for several decades of medical

* Comments prepared in response to "Controlling Health Technology" by Clifton R. Gaus and Barbara S. Cooper.

Editors' note: Dr. Heyssel's discussion is in response to issues raised by Gaus and Cooper in their paper as presented at the symposium. In revising their paper for this volume Gaus and Cooper greatly condensed their original discussions of the possible causes of the rise in medical care costs and the possible role of medical technology in improving health status. Many of Dr. Heyssel's references therefore are directed to their original discussions which do not appear in this volume.

research which has been translated into more effective medical care. The desire on the part of insurers, the government, and, presumably, the public to cover the extraordinary costs of the results of that research led to broader coverage, cost reimbursement, and ultimately to full insurance coverage, not the other way around. Under Medicare, renal dialysis and transplant coverage were added because research made treatment of end-stage renal disease available. The research was not carried out because there was a cost reimbursement mechanism for treatment any more than the Blalock-Taussig operation was a result of anticipating the day when we would have cost reimbursement. While cost reimbursement has the singular effect of accelerating the diffusion of technology, and while the lack of any effective forces to restrain investment in unneeded and reduntant facilities is deplorable, blaming a payment mechanism for the existence of an expensive technique to save or prolong lives is an exercise in sophistry.

Second, while there is the usual and tiresome talk of "prestige-seeking trustees and administrators" and physician influence, a very important human element is omitted. The desire to save lives and to make living more comfortable or more productive for those who have a disability is a desire shared by most people, whether they are trustees, physicians, or the average man or woman. That desire has created a demand for more sophisticated and better medical care and has been concurred in by the Congress and Executive branch. The creation and generous funding of the National Institutes of Health (NIH) after World War II, which accelerated the growth of technology, was presumably a response of government to a perceived need or demand of the people. To some extent the government helped create the needs or demands. The Department of Health, Education, and Welfare's public relations efforts and the NIH's lobbying have been fairly effective! In terms of balance, then, I believe the medical system has responded to the desires of the people and the government. It is very easy and politically wise to blame the doctors, the hospitals, and the administrators for the modern dilemma of the medical commons[2] — but not very constructive.

Third, other phrases bother me, such as "the application of extraordinary and expensive means to slightly extend the life of someone in a hopeless situation." Who defines a term such as "slightly" or who defines a situation as "hopeless?" What is hopeless? Cardiac arrest was hopeless twenty years ago. It is not today; yet a fair number of patients vegetate after effective cardiac action is restored. Severe intracranial hemorrhage is not as hopeless as before; but again, some vegetate and some get up and walk. Subacute bacterial endocarditis was hopeless thirty years ago; now we can cure it and, if necessary, replace a valve at considerable expense. What is slightly? In an average life span of threescore and ten, do five more years of meaningful life constitute "slightly" extended, or does one more year constitute "slightly"?

Fourth, the statement is made that Medicare statistics show that about one-quarter of all outlays are spent for persons in the last year of life, as if a different result were to be expected. What is so extraordinary about that? That may not be a cost-effective way to spend our money, and perhaps a different result is desirable. It is clear, however, that more money will be spent on very sick people over 65 than on those people over 65 with less serious disease. Presumably it costs more to care for the very sick than for those who are not so sick, and the risk of death is higher in the former. Certainly an episode of a chronic and terminal illness including nursing home care for the elderly is more expensive than an episode of an acute, self-limited illness. The issue of spending a large sum on those who benefit little and of expending money from which some may say society benefits little is a "whether or not" issue, not a question of high-cost technology. Put simply, it is whether or not we, as a society, choose to pay for medical care for chronic and often terminal illness in people over the age of 65.

Fifth, it is worthwhile to analyze a statement by Martin Feldstein that "our current methods of hospital insurance have encouraged hospitals to raise wage rates and to increase the sophistication and expensiveness of their product more rapidly than the public actually wants."[3] With regard to wages, hospitals do not exist apart from the rest of society and its issues of equity in wages and salaries. With regard to what the "public wants," I do not know what survey of public preferences Feldstein refers to, but nowhere in his essay do I find evidence that he had access to a scientific survey of people's preferences relating to such questions as: Do we want grandmother/father treated for cancer at age 66? Do we want mother/father to have renal dialysis and transplantation? Do we want laboratory testing which defines with precision the cause of hypertension and dictates its treatment as opposed to giving drugs or doing surgery without relation to causation?

The only support I could find for that statement in Feldstein's book is his comment in a footnote that "the rapid growth of the Kaiser Plan supports the view that when patients can choose in advance, many of them will select the system in which costs and in which *the quality* of care is lower."[3] (Emphasis mine.) Feldstein defines *quality of care* in the Kaiser system generally as the *number* of hospital days rather than the cost per day. That is a rather dubious view. First, I doubt seriously that the Kaiser people think they are offering a product that has lower quality! In any event, number of bed days per 1,000 in a population has nothing to do with the technology of care. In the Kaiser system, if a patient needs open-heart surgery or radiation therapy, high-technology care if you will, it is made available. I presume they do laboratory tests which they believe will help them distinguish renal vascular hypertension from aldosteronism, etc. But to use the effect of *a system of medical care* on use of bed-days, laboratory testing, and general resource allocation within the system as evidence that the public does not want expensive medical care when it is perceived as necessary by the physician, and is understood by the patient as desirable, is twisting and turning to support a viewpoint rather than using facts to support a reasonable conclusion.

Finally, about the only thing I find in Gaus and Cooper's paper that I can agree with regarding the problem and its cause is the point quoted there from Redisch's treatise on "Cost Containment and Physician Involvement in Decision-Making."[4] I agree completely that "control measures to hold down the rate of inflation of hospital cost, if aimed solely at the hospital, will be disappointing." I will go further: doomed to failure.

The effect of increased use of expensive technology on the health status of Americans

In the section of the Gaus/Cooper paper entitled "Technology and Health Status," the question is examined of whether it is possible to show improvement in health status as a result of increased use of expensive technology. Death rate per 100,000 population is one measure of health status in a population, and changes may or may not be attributable wholly or in part to some intervention or another. Much of the change cited in lowered mortality rates in heart disease in the last decade is probably not the result of sophisticated heart surgery, coronary care units, or emergency vehicles with monitoring and direct communications with hospital emergency rooms. But to say that medical care has little to do with changes in crude indices such as deaths per 100,000 population ignores some changes that are important to individuals.

Health status is certainly something other than death rates. When we deal in aggregates we can ask such questions as, how much "improvement" did our $10 billion in 1976 buy us over 1966? In the aggregate, that becomes an almost impossible question to answer, as is pointed out by the authors. If, however, you look at individual interventions in terms of health status, each of those individual interventions added up to the $10 billion being talked about, and the question is whether none, some, most, or all of it was worth it for the individuals. It is all summed up in the statement attributed to Barnes[5] that "we are now putting tens of thousands of people in the hospital each year at a cost of $43 million to save each additional life." That implies that hospitals are there simply to save lives and that that is their only measure of effectiveness. The book *Costs, Risks, and Benefits of Surgery*, from which that quote is taken, is careful to distinguish individual from societal values and to include the betterment of the quality of life for an individual as a benefit as well as lifesaving. The statement as quoted almost presumes that there is no merit in ameliorating disease if you cannot cure it.

Control of technology as a means of cost containment in health care

As put by Gaus and Cooper, the operative question at this conference is Barnes' question, "How many more lives could be saved if the $43 million per individual life saved were used more wisely?" It is that question of how we spend available dollars that we are concerned with: How much are we willing to spend on medical care, individually and in the aggregate, and for what purpose? Who is wise enough to make the choices? On what basis? Through what process? Dealing with the cost of technology and the choices of how to spend limited resources raises moral and ethical issues that will begin to spark a major societal debate. The debate should at least be objective and not couched in "whose fault" rhetoric. It has major social implications in terms of our perception of the kind of people we are and the kind of society we live in. When we make the decision that something is not worth doing monetarily for society as a whole, we are also making thousands of decisions for individuals.

Gaus and Cooper propose a number of Methods of Technology Control to deal with the problem. The basic approaches, advocated with varying degrees of enthusiasm, are: planning controls and reimbursement limits, direct market entry (the FDA model), and physician training and consumer education. While each of the approaches or combination of them has its appeal, each also has consequences which should be foreseen.

Control of capital expenditures and reimbursement limits is a way of saying "rationing of resources" — putting the control on the side of supply. No one is going to argue that elimination of some redundant facilities, cutting out marginal open-heart surgery programs through recertification programs, etc., is not a way to save money. But the only significant money that is going to be saved in the long haul will result from setting the limits of spending at some level below that of demand, which is what will happen if we take the limitation of capital approach. In effect, we will have rationing through a queuing mechanism.

"Procedure reimbursement limitation," an alternative strategy, will have the effect of freezing the system in place. Proposed are protocols for testing and putting into practice all new uses of health technology. I assume that this means a range from major techniques such as computerized axial tomography down to and including the various $2.50 per test determinations introduced each year, which in total cost a lot of money. The problem with that approach is that it always must be tied to the existing modes of practice. I realize that Gaus and Cooper, in their section on protocols and reimbursement changes, end by saying, "Perfect protocols could probably never be developed to handle every circumstance, so that flexible application would be needed." I think it is the experience of most people outside of government that flexible application of any regulation has certainly not been the mode of operation to this point. Government, undoubtedly working through physicians' panels and so forth, will instead become deeply involved in the practice of medicine, as opposed to developing and regulating payment and quality, control of fraud and the like. If that had been the mode of operation in 1800, would we still have Benjamin Rush and the wonders of calomel, bleeding, and purging? And what could be the cost of this regulation? Will regulation through protocols be cost-effective?

Another suggestion is direct market entry regulation, "the FDA model." A side effect of federal regulation of testing and bringing new drugs into the marketplace has been to create a rise in development costs for new drugs and an unaudited, but probably real, reluctance on the part of manufacturers to risk money on developing drugs that are less than certain to be finally approved but which could bring about the greatest advances. What is worse is the fact that major drug firms are now going out of this country to test market drugs and do phase III testing in less restrictive societies, both developed and underdeveloped nations. Quite aside from the moral issues raised by that (i.e., should this country use other populations as test subject?), we may be denying ourselves earlier advances. The thalidomide story alone is enough to make anyone grateful for an FDA, but what is done should not result in either undue and costly delay, or failure of development through overly restrictive testing and/or pushing the hazards of testing onto other societies.

Finally, with regard to physician training, there is a real dilemma regarding specialization. Increased knowledge in any field tends to force specialization; but on the other hand the real economic advantage accruing to physicians through specialization cannot be denied, and in some instances, at least, it is likely that the difference between payments to accredited specialists and those to "generalists" has probably been a real factor in the establishment of specialty boards. I hope that we still believe that while increased knowledge brings its problems it is better than unchanged or increased ignorance. While one can argue that specialist medicine is more expensive than general practice medicine, it is also true that specialists are better than generalists at taking care of cataracts in old people or handling respiratory distress in prematurely born infants. Specialization is not a clever plot of the AMA to garner a greater share of the Gross National Product, any more than it is a plot for legal firms to have specialists in labor law, tax law, etc., or economists to specialize in one area or another. It has to do with the body of knowledge and how much any one person can effectively deal with. To hear a call for a return to teaching "black bag" medicine can only cause me to ask whether, in the name of cost containment, we really wish to put the clock back to 1900. The question here is more related to overall numbers of specialists and their geographic distribution than the control of technology through returning to "black bag" medicine. The issue is probably better dealt with through changes in reimbursement mechanisms than through curbing, if it were possible, specialization.

It appears that most of the proposals put forward for curbing technology and its costs would cause medicine to be, as Dickens put it, "skewered through and through with office pens and bound hand and foot with red tape."[6] We save money, but at an unknown price in terms of lives made better, lives saved, and challenges met. More importantly, what will be the ultimate effect on our perception of our society if the aggregate cost benefit to society is the basis for decision-making, rather than the benefit to individuals in that society? To put it crudely, one solution to the problem of controlling technology costs resides in deciding *not to do* things *we can do* for individuals. We should not allow the oft-cited fact that the results of our efforts are imperfect, or even the fact that on occasion our methods are misguided or wrong, to be used to obscure the distinction between making decisions for the collective versus decisions for the individual.

Cost-benefit analysis as a means toward control of technology

To be less critical and more fair, it is reasonable to ask the question of whether what we are doing is worth what we are paying. Thomas Preston states[7] that the value of vein bypass surgery for coronary artery disease is unproven, and that the procedure is not established as effective therapy. Thus far, in his view there is no evidence that it is beneficial when applied on the scale used in this country. There is equally no proof that it is unsuccessful or of no net benefit. That is an important distinction, since lack of proof of efficacy does not mean proof of no-value.

Preston's problem is the same one that Gaus and Cooper have, at least in part. Good scientific investigation was not done to evaluate the procedure before it came into such common and widespread use, which Preston estimates as a minimum of 60,000 operations per year, at an annual cost of nearly three-quarters of a billion dollars in this country. Preston's solution to the problem is not more government regulation of technology but better self-regulation of the profession through use of established scientific methods for evaluation.

But even if Preston's solution were possible, the central issue of the cost of that procedure in relation to aggregate health care costs, and other equally valid or more urgent societal needs, would remain. If coronary artery surgery were uniformly agreed to be effective in ameliorating the effect of the disease, either through prolongation of life or through a more comfortable and productive existence without significant life prolongation, the procedure would still be very expensive.

There are models for measuring cost benefits or cost-effectiveness in medicine. In Bunker, Barnes, and Mosteller's book on *Costs, Risks and Benefits of Surgery,* Weinstein et al.[8] conclude, a bit differently from Preston, that for the individual patient coronary artery bypass surgery is probably the optimal method of treatment. From the point of view of resource allocation for the collective, the procedure appears to be less attractive and even perhaps a poor investment as opposed to other choices. In Weinstein's analysis, "The cost per year of life saved or comfort achieved in this procedure clearly exceeds the level of funds generally available elsewhere in the health sector and considerations of earnings or willingness to pay by the individual if the patient paid out of pocket."

These peculiar and relatively new concerns are examined in a futuristic manner in a paper entitled, "Allocation of Artificial Hearts in the Year 2002: Minerva . . . versus the National Health Agency," by George Annas.[9] He examines a hypothetical U.S. Supreme Court decision concerning the "National Health Agency's" regulations, which had in 1997 established a system for allocating artificial hearts to those whose lives could be lengthened by implantation. Minerva challenged the constitutionality of allocation of a lifesaving procedure. The agency averred that allocation was needed, since the expense of providing the hearts for everyone who might benefit was more than the United States was able or willing to spend in the year 2002.

The system involved allocating artificial hearts to candidates who met the following criteria:

> He or she must be more than 15 years old but less than 70 years old, be capable of living at least ten additional years if the implant procedure is successful, and not be a chronic alcoholic or drug addict.

Once a patient had qualified, his or her name was immediately placed, by a physician certified by the National Health Agency as a qualified thoracic surgeon, on a national waiting list for artificial hearts. The patients were then selected from the list at random at the rate of 400 a week and, if lucky enough (or unlucky enough), they would remain on the list until they died, or failed to meet the criteria, or could have the artificial heart implanted.

The majority opinion in Annas' hypothetical case rules that Congress had the right to ration a scarce resource and that it was in the public interest to ration. Since thoracic surgeons were in short supply because of government restrictions imposed on the number of surgeons trained in prior years, they would be turning all their attention to this area, rather than to other needed services. The Court held further than random selection of patients did not violate due process rights, and also that an expensive medical technology such as an artificial heart implantation could properly be labeled a luxury, even though it did sustain life, and that the State had no need to provide it to all of its citizens. One of the assenting judges joined the majority only because he believed that to refrain from rationing the procedure would open up a black market; he really believed, however, that all artificial heart transplants should be outlawed because they were inhuman and inhumane, and also because there could be no such thing, in the case of lifesaving procedure, as informed consent.

The dissenting opinions pointed out that the criteria listed by the government were used to discriminate against some individuals on the basis of social worth. Patients with a history of mental illness or with criminal records, those unemployed, and those with an IQ of lower than 80 were generally underrepresented on the list even if they did meet the other criteria, because bias was at work. The dissenters felt that to characterize an artificial heart as a luxury was playing with words and that "today's luxury is tomorrow's necessity." One justice believed that the allocation of artificial hearts to prolong life simply misdirected scarce resources which could be better spent in other areas; but if they were to be made available, the ability to pay would be a better allocator of 20,000 hearts a year than regulations which were administratively clumsy, somewhat arbitrary, and inevitably discriminatory.

The problem that Preston, Weinstein, and the Supreme Court in Annas' paper all have is not whether it is possible to do cost-benefit or cost-effectiveness analysis, but whether it leads to understandable social equity. Is it the proper basis for decision making?

General comments and some alternative suggestions for cost containment

There is no question that we have a problem with rapidly rising health care costs. Moreover, there seems to be consensus that the rise is unsustainable and in part unjustified. If that be the case, then the issue is cost containment, not technology, mismanagement, or other bogies. It may be that focusing on technology as the culprit is politically easier than dealing with the wages and salaries of health care workers, the increase in numbers of physicians, and the untrammeled freedom of health care professionals to practice where and how they wish. However, the notion that it is easier to deal with technology is illusory. To do so will lead to greater problems than a more general cost containment strategy. Annas' paper does lay out the choices with regard to control of technology, based on cost benefit analysis of cost-effectiveness analysis, and the societal dilemmas that each approach will lead to. The choices with regard to a given procedure are really four:

1. Ration or allocate through regulation
2. Do not do it for anyone — outlaw the procedure
3. You can have it if you can pay for it
4. Don't do anything and hope the problem solves itself.

Three of these choices, I reject; the last one, a laissez-faire approach, is unacceptable. Choice Three, makes allocation strictly a matter of money, i.e., if you are poor, you do not get the treatment; if you are middle class, you can go broke trying; and if you are wealthy, you do get treatment. Choice Two, outlawing certain therapies or procedures, will ultimately have the same effect as the "ability to pay" decision. Since we already have offshore "insurance companies" and "flags of convenience," I know where we will find the heart surgeons!

That leaves us, unfortunately, with allocation and rationing through the regulatory approach, which may have all the worst effects of choices Two and Three. On the one hand it will basically require an all-pervasive and powerful central "National Health Agency" and will lead to the demise of any semblance of a private sector in health. At the same time, over a few years it will probably lead to the development of a new and competing "you can get it if you can pay for it" system.

Even when the regulatory approach is combined with FDA premarketing entry and the outlawing of certain technologies and therapies to avoid the possibility that the wealthy will be able to buy what the government will not underwrite for others, I doubt that the problem of black markets, offshore operations, and the privilege of wealth can be overcome. After all, even rationing on a random selection basis — first come, first served — will be subject in medicine to the same forces that influence maître d's to move someone to the head of the line in a busy restaurant.

Because of those problems, I do not believe that the direct regulation of technology per se is a wise policy choice regarding cost containment in health care. Rather I would propose fundamental changes in the reimbursement of providers, changes in tax laws to make the consumer aware of the cost implications of the available choices, changes in benefits covered, mandated changes in the evaluation of technology, restructuring of the system governing delivery of capital-intensive high-operating-cost technologies, and changes in medical education. To be specific:

1. We should not, for the present, pass any new law or write or rewrite regulations relating to the entry of new technology into medical care. We should continue to develop technology, but spend some time

developing the control of its use through evidence concerning effectiveness.

2. To draw on Preston's[7] ideas, we must have objective, scientific validation of the efficacy of procedures, tests, etc. before their general application. We need to establish the mechanism for ~~this validation~~ and then develop effective sanctions against nonvalidated practice. The issue should be protection of the public, not limitation of medical practice.
3. We need to turn medical education toward more emphasis on scientific evidence concerning the relative effectiveness of diagnostic testing and therapeutic intervention and insist on rigorous evidence to support claims of the superiority of one method of diagnosis or treatment over another. Sanctions again must be real.
4. We must shift the fee system away from large payments for surgical and other procedures. The current indemnity system for surgeons' and physicians' procedures has the effect of leading to excessive surgery, the overuse of other procedures, and the overpopulation of certain procedurally oriented, high-income specialties.
5. With regard to expensive, high-technology tests and procedures, we must move away from cost reimbursement for hospitals and toward regionalization of facilities. The existing planning laws need added strength.
6. We need to establish a basic but clearly limited set of covered health benefits which all third-party payers must offer. There should be limitations on hospital coverage based on diagnosis and medical condition, with no payment for some conditions, perhaps partial payment for certain conditions, and full coverage for others. Purchase of insurance-covered services over and above this must be paid for by the recipient with no tax deductions, or payment for the service be counted wholly as taxable income if provided as a fringe benefit. For special groups, the poor, disabled or handicapped, children, and the elderly, coverage for special services should be added by the government.
7. We should restructure graduate medical education by declaring certain graduate medical education programs as surplus or unneeded in whole or in part, and eliminating reimbursement payments to hospitals that support those training programs.

In summary, to attempt to control the growth of technology through regulations as proposed by Gaus and Cooper *will not* limit what we know, what we can do, or even ultimately whether we do it — for those who can pay. It is highly likely that it will divide who gets what in medical care — or at least in ameliorative and life-lengthening therapy — along economic lines. It is likely that we will make the system so rigid that ultimate technology will not replace the half-way technology of today, that the introduction of cost-effective technology will be so slow that costs will not be saved, and that in fact waste will result.

We do need system changes; but the argument made here is that the unforeseen consequence and cost of regulation of technology is likely to be higher than a general cost containment strategy aimed at changes in reimbursement, changes in practice through proper evaluation, and changes in specialty distribution.

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Observations on health care technology: Measurement, analysis, and policy*

Herbert E. Klarman

Introduction

Both papers under discussion — by Alain Enthoven and Roger Noll and by Clifton R. Gaus and Barbara S. Cooper — are oriented toward policy, and will be discussed accordingly. However, both papers seem to be rooted in certain assumptions regarding the sources of increase in hospital care expenditures and the implications of systematic analysis for policy, which deserve to be spelled out and examined. Accordingly, Part I of my paper deals with the arithmetic of measuring trends in hospital care expenditures and the several component factors. Part II presents a brief discussion of cost-benefit analysis and its potential application to health care technology, as requested in my invitation to the Forum. Part III addresses the policy options proposed in the two papers.

The data: calculations and estimates

Neither the paper by Enthoven and Noll nor that by Gaus and Cooper states what health care technology is. Perhaps that is because it appears self-evident. Yet, technology may be many things, such as changes in the application of existing modalities (Enthoven and Noll) or virtually all operations and procedures (Gaus and Cooper).

Both papers focus on the short-term hospital. Gaus and Cooper equate changes in technology with changes in factor intensity, following a footnote in Martin Feldstein.[1] I do not believe that the extent of correlation between technology and factor intensity is knowable *a priori*; that can be determined only case by case, as Altman and Wallack suggest.[2] However, to understand the increases in hospital care costs over the past decade, we do need some sense of the relative contributions to them of price increases versus increases in factor intensity. I have therefore undertaken the following calculations and estimates, which employ the same basic data as Gaus and Cooper, and then made certain specific adjustments.

As background for their paper, Enthoven and Noll note that per capita real, age-adjusted expenditures for short-term hospital care rose by 80 percent between 1965 and 1975. Applying the Feldstein-Waldman method,

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*Discussion of papers by Clifton R. Gaus and Barbara S. Cooper, "Controlling Health Technology," and by Alain Enthoven and Roger Noll, "Regulatory and Nonregulatory Strategies for Controlling Health Care Costs."

Gaus and Cooper report that in the decade 1966–76, changes in factor intensity accounted for one-half of the increase in patient day cost; for the year 1976 they calculate that this factor amounts to $10 billion, or a range of $8 to $12 billion.

For a better, more systematic grasp of the data on expenditures for short-term hospital care, I have prepared the following tables for the interval 1966 to 1976, based on data kindly furnished by Barbara Cooper. Table 1 shows the annual rates of increase in several factors — population, per capita utilization, adjusted patient day cost, etc. A percentage distribution of the respective contributions of these factors to the increase in total expenditures for short-term hospital care is shown in Table 2. Two steps that intervene between Tables 1 and 2 should be noted: (1) payroll items are weighted at 61 percent and nonpayroll items at 39, as of 1966; and (2) here and there, one or more tenths of a percentage point are lost for technical reasons: the arithmetic has been transformed from a process of multiplication to one of addition.

Table 1

Annual rates of increase, various factors, in expenditures for short-term hospital care United States, fiscal years 1966–76

Factor	*Annual rate of increase*
Total expenditures	15.8%
Population	0.9
Utilization per capita	1.6
Adjusted cost, patient day	12.9
Prices	
Wages	8.0
Consumer Price Index	5.7
Inputs	
Employees	2.8
Other	9.3

Source of data. Barbara Cooper, Health Care Financing Administration.

Table 2

Percentage distribution of contribution of various factors to increase in expenditures for short-term hospital care United States, fiscal years 1966–76

Factor	*Percentage distribution*
Total	100%
Population	5.8
Utilization per capita	10.4
Adjusted cost, patient day	83.8
Prices	48.0
Inputs	35.8

Source. Table 1 and text.

One-sixth of the increase in expenditures for short-term hospital care in the decade 1966–76 is due to an increase in utilization and five-sixths is due to the increase in adjusted patient day cost, according to Table 2. In turn (not shown in exactly this form in the table), changes in prices contributed 57 percent of the increase in patient day cost and changes in inputs or in intensity, 43 percent.

In view of the widespread impression that aging of the population is an important influence, as well as to accommodate Enthoven and Noll's interest in age adjustment, I have calculated the contribution of the aging of the population to the increase in utilization of short-term hospital care. Two different estimates emerged. One allows for the increase in the percentage of aged person (65 years and over) in the total population, and holds per capita use constant; the other allows for the change in the composition of population and also takes account of the increase in per capita use by the aged. For the two approaches, the contributions of the aging of the population to the increase in total utilization are 10 and 16 percent, respectively. Applied to the figure of 16.2 percent in Table 2 (5.8 + 10.4), these are modest contributions indeed — between 1.6 and 2.6 percent of the increase in total hospital care expenditures.

The question immediately arises: How can this finding be reconciled with the well-known fact that at a given time the aged use so much more hospital care per capita than the rest of the population? The answer is twofold: (1) the aged still constitute only 10 percent of the population; and (2) this fraction increases rather slowly over time.

I then proceeded to enter several adjustments to Table 2, which bear on the relative contributions of changes in prices and in factor inputs to the increase in patient day cost. Data to support these adjustments are not readily available; no systematic time series exist. Nevertheless, the case for making the adjustments is so compelling that approximate estimates are better than none. It is fair to note also that they are largely on the conservative side.

The adjustments, then, and the data from which they are derived, are as follows:

1. Data on fringe benefits for the year 1976 were published in *Hospitals*, and the American Hospital Association has kindly furnished unpublished data going back to 1971.[3] For 1966, I have estimated the figure by extrapolating the available data backward and by making use of other, more limited data for that year. The figures on fringe benefits for 1966 and 1976 were transferred from nonpayroll to payroll expenses, where they belong.
2. In two intervals for which nationwide data are available — 1963 to 1966 and 1966 to 1969 — the level of skill of hospital employees declined, as calculated by Feldstein-Taylor.[4] Arbitrarily I halved these authors' annual differential of 1.6 or 1.7 percent and extended it over the entire decade.
3. The recent tendency of hospitals to contract for certain services was taken into account, on a minimum basis.[5]

4. The mark-up and acceleration of capital depreciation in the 1960s were taken into account, following Foster.[6]

Still other possible adjustments were considered, especially in the length of work-week and work-year of hospital employees, but could not be carried out.

Table 3 presents my adjustments to the annual rates of increase in Table 1. The shift of fringe benefits from nonpayroll to payroll raises the proportion of payroll to total expenses in the base year from 61 to 66.2 percent. Table 4 shows revised relative contributions of increases in price and in factor inputs to the increase in adjusted patient day cost. After the adjustments, the contribution of the increase in price rises from 57 to 67 percent and that of the increase in factor inputs falls correspondingly from 43 to 33 percent.

These estimates are the best I have been able to make with my own resources at this time, and I do not claim that they are precise. However, I do believe that they clearly show that the relative contribution of price changes to the increase in cost has been generally underestimated and that of changes in factor inputs overestimated. One would expect that a shift in the empirical findings from one-half to one-third might have a bearing on public policy. It is important that the process of estimating begun here be continued, expanded, and refined by the responsible official agencies.

Analysis

This part consists of two sections. It draws heavily on an earlier paper by me.[7]

Cost-benefit analysis

Cost-benefit analysis is a form of expenditure analysis applicable to the public sector, which is analogous to, and a substitute for, supply-demand analysis in the private sector. Its intellectual sources are diverse, including the political-bureaucratic calculations of the Army Corps of Engineers in its

Table 3
Adjustment factors for estimating relative contributions of prices and inputs to increase in adjusted patient day cost, fiscal years 1966–76

Adjustment factor	*Average wage*	*Number of employees*	*CPI*	*Other inputs*
Data, Table 1	8.0%	2.8%	5.7%	9.3%
Fringe benefits	+0.6	—	—	−0.3
Skill level, employees	+0.8	−0.8	—	—
Contracting out	—	+0.2	—	−0.2
Depreciation	—	—	+0.8	−0.9
Adjusted total	9.4%	2.2%	6.5%	7.9%

Source. See text

Table 4
Adjusted data: Percentage distribution of contribution of price and inputs to increase in adjusted patient day cost, fiscal years 1966-76

Factor	Annual rate of increase	Weighted annual rate of increase	Percentage distribution
Prices	—	8.4%	67.1%
Wages	9.4%	6.2	—
CPI	6.5	2.2	—
Inputs	—	4.1	32.9
Employees	2.2	1.4	—
Others	7.9	2.7	—
Total	—	12.5%	100.0%

Source: Table 3 and text

evaluation of water projects, the highly theoretical "new" welfare economics, decision making in business on capital expenditures, and program analysis for national defense through systems analysis and cost-effectiveness analysis.

In the health care literature, reference is sometimes made to cost-benefit relationships when they are not germane. For example, if a program or project produces a given service at a lower cost per unit than another, it is preferable, without further ado, simply because it is cheaper. This is a good Anglo-Saxon word.

But the essence of cost-benefit analysis is that it goes beyond questions of efficiency or good management in the financing or provision of a good or service to questions of outcomes and their values. If a program or project yields a set of outcomes that is worth more than that of another program, or costs less, or yields the greatest value of net benefits, it is preferable. In cost-benefit analysis all benefits and all costs of a project are to be ascertained and valued, to whomever they may accrue. Although discussion of distribution — who gets what and who pays — is entering into the literature, definitive treatment of the matter is still rare.

In the allocation of resources among alternative public programs, the aim is to undertake all programs that yield a surplus of benefits over costs. As a practical matter, a budget constraint is likely to prevail, and the aim then is to undertake in rank order the projects with the highest ratios of benefits to cost (properly defined), until the available funds run out. It is therefore necessary to delineate all the programs to be compared; measure the projected costs over time for each program; determine the projected outcomes over time for each program and value their benefits; and render the streams of costs and of benefits for each program commensurate by means of a discount (interest) rate.

The calculation of costs is more or less straightforward, especially if all costs fall within the program's own budget. However, before benefits can be calculated, the physical outcomes must be ascertained and measured in whatever units are appropriate. Examples of units of health status outcome are gains in life expectancy, reduction in injury or disease, improvement in function, lessening of anxiety, or palliation of pain. Determing the effects of programs is an absolute prerequisite to the valuation of the benefits of health care programs and of other, competing programs.

The next step, that of valuing benefits, is rather subtle and tricky. About 1960 a consensus emerged among health economists. Benefits were seen in terms of costs (the burden now being borne) that would be averted if a program were successful. These costs were of three types:

1. *Direct costs*, health care expenditures that would be saved.
2. *Indirect, tangible costs*, losses in earnings that would not occur.
3. *Intangible costs*, the pain, grief, discomfort, etc., that would be avoided.

The direct costs component is clear; problems of calculation arise, but the task is certainly feasible, as demonstrated by Dorothy Rice's work.[8] Intangible costs receive lip service, but are usually disregarded. The core of the typical exercise in cost-benefit analysis of health care programs lies in the calculation of indirect, tangible benefits, as measured by earnings. This method and the findings it yields are widely applied.

In recent years the method has evoked two sets of criticisms. One, the earnings approach is anti-egalitarian, in that it puts a lower value on the lives of aged persons, blacks, or women, who have lower earnings than young adults, whites, or men. In enacting public programs we frequently refuse to act on the findings that this method entails. Two, and perhaps more fundamental, a person's appraisal of the value of his own life is not based on his or her earnings potential. Perhaps a person's earnings are relevant to others; if so, they would be only after that person's own consumption were deducted. A person's valuation of his own life and the values all of us put on our own lives reflect what we would be willing to pay for a statistical reduction in the probability of dying during a specified interval, say the next year. Such an exercise would be difficult to carry out, although one can confidently predict that the resulting figure would be positive. However, the value attached by the rest of society entails a deduction of consumption from earnings, and the figure for this component might turn out to be negative. The aggregate value of the two components is not known, and is perhaps not ascertainable at this time.

For programs involving effects on mortality, I am therefore disinclined today in my own work to conduct a full-fledged cost-benefit analysis.[9] Nevertheless, a limited but still strong analytical statement can be made. The preferred program is one that yields the same desired outcomes for the lowest cost. We have now entered the realm of cost-effectiveness analysis. Here measurement of the effectiveness of programs remains an essential step. When effectiveness is not measured, the rest of the exercise is futile. However — here I concur with Enthoven and Noll — the typical problem in health care technology is not likely to be total ineffectiveness, but rather one of diminishing effectiveness of a program as total utilization increases.

An important point about cost-effectiveness analysis is that when different types of outcome are involved and their benefits are not valued, it confuses matters to say that one program is cost-effective and another is not. One might just as well say, I like the one program and do not care for the other.

Perhaps the politician — the decision maker — could get away with such statements of likes and dislikes; the policy analyst cannot. In the absence of valuation, what can the analyst do? He can calculate the costs of different programs and comment on the magnitudes involved. Sometimes the sums are large enough to warrant being related to the total GNP. Here he can point out the implications of choices among programs, if they are true alternatives for one another. Often the statement that this nation cannot afford a particular program merely reflects an implicit personal judgment of what is worth doing.

Applications to technology

I trust that this discussion of the ground rules of cost-benefit analysis is clarifying, but by itself it can make no contribution to a substantive discussion of health care technology. For, in general, there are no *a priori* grounds for believing that new technology will serve to increase or reduce expenditures. It depends on the specific case. For example, adoption of the practice of early ambulation after surgery and the consequent reduction in the average length of patient stay in hospitals after World War II meant a large decline in cost per stay and a small increase in cost per patient day. The magnitude of this effect has been calculated.[10]

Automation of the laboratory has served to reduce cost per test, but at the same time the volume of tests has risen. The net effect seems to have been a steady upward creep in cost per case or per patient day. (This impression is supported by Anne Scitovsky's paper.[11])

Using disposable supplies in hospitals should either cost less or improve the reliability of supplies. The same is true of equipping an entire hospital with oxygen outlets, except that here life-cycle analysis of the cost of the service is appropriate.

A new procedure like hemodialysis of patients with end stage kidney disease increases total health care expenditures, for it must be continued for the remainder of the lives of persons whose life expectancy is extended. Home dialysis can yield some savings in the aggregate, but raises patient day cost in the hospital to the extent that the latter now serves as a training center for all new patients. Kidney transplantation costs much more per treatment, but reduces expenditures per life-year gained.[12]

Always there is the temptation — and tendency — to extend diagnosis and treatment to additional numbers of patients, as capacity expands. This tendency is reinforced by prepayment with its dual price system (see below).

Faster dissemination of new developments also makes a difference, as does the building of new, complete hospitals in the suburbs, with complex facilities. When a piece of technology is cost-raising, its contribution to higher expenditures will be greater when the rate of diffusion is more rapid. A rapid rate of diffusion is likely to hasten the adoption of half-way technologies, and the larger the number of hospitals that adopt these technologies, the higher will be the average rate of increase in expenditures.

If the rate of diffusion is fast, any control effort requires early identification and assessment of the technology and its application. Such identification may not be very difficult in terms of what is technologically possible over the coming decade or so, but it is difficult in terms of guessing the probability and areas of application. The imponderables of technological assessment are bound to be greater when it is undertaken in an early phase of development. Unintended effects are hard to conceive of, and the questions posed initially may miss the mark.

With big, visible pieces of equipment, I should not minimize the advantages of bureaucratic delay as a component of policy. To deal with small, creeping changes in technology, however, it is necessary to engage the mechanism of health care financing.

Public policies

I turn now to alternative policies for dealing with the increase in hospital care expenditures, holding in abeyance their applicability to health care technology.

The first very important question to be faced is why the large increase in hospital care expenditures is viewed as a serious problem. The standard answer today is that increases in factor inputs or intensity have failed to yield a commensurate return in the form of improved health. This case, which is usually argued in terms of the death rate, is becoming more difficult to sustain in the face of the appreciable reductions currently being reported for several major causes of death and the total death rates. Increasingly, it is suggested that changes in life style, rather than increases in the volume of health care, may be yielding this dividend. Surely, ingenuity in research design should enable us to disentagle the two influences. In addition, let me point to the substantial increases in price and ask whether inquiry should not be made into the extent to which the hospital industry's wages and fringe benefits may have caught up with remuneration in the same or comparable occupations in other industries. Let us take note, too, of the wide geographic variation in health care utilization that exists today, without any apparent relationship to health status; the probable inefficiencies in hospital operation that were introduced with the large-scale adoption of cost reimbursement on a retrospective basis; and the need to economize in the production of existing services if certain services, particularly for long-term patients, are to be expanded. In my view, these considerations warrant a strong interest in curtailing the rate of increase in hospital care.

The two papers by Enthoven and Noll and by Gaus and Cooper discuss, broadly, four sets of cost-curtailment policies: more copayment; alternative delivery and financing systems, such as the Health Maintenance Organization (HMO); planning and regulation; and professional and consumer education.

Copayment

Central to the proposal to expand reliance on copayment is the belief that the dual price system under the prepayment system emits the wrong signals to consumers and providers. When a service is used, the price seems low, everything looks cheaper than it really is, and everybody winds up asking for, and getting, more of everything. This analysis derives from Martin Feldstein.[1]

Provider vanity and physician influences are said to reinforce this effect. However, these factors have long been operative in the hospital industry. What was new in the mid-1960s, when the acceleration in cost increases began, was the influx of many additional dollars and the more widespread of cost reimbursement.

It is noteworthy that a review of the available estimates of the proportion of third-party payments to total hospital care expenditures shows an increase of only 6 percentage points between the year 1966 and the year 1967;[13] for short-term hospitals alone, the estimated change was even smaller.[4] The major shift toward third-party payments had taken place earlier, between 1950 and 1966, from 51 to 76 percent;[4] recent years have witnessed a small and steady continuing rise. But the point is that the interval immediately surrounding the implementation of Medicare and Medicaid saw only a modest rise. At the same time, according to an early estimate of mine, the proportion of all short-term hospital patients days reimbursed at cost rose by 75 percent or more.[14]

Accepting as fact the argument that increased prepayment alone led to the rise in expenditures, Enthoven and Noll deal with, and dispose of, the case for more copayment. They object to more copayment on the ground that it is not equitable and that it cannot be operative beyond whatever point is established as the maximum financial liability for an individual or family.

I agree. I take it that Gaus and Cooper do not deal with this policy option because they do not regard it as a serious one. Let me add that many Americans buy supplementary health insurance to defray their out-of-pocket payments; the aged pay for this themselves, without any employer contribution. Also, copayments would probably be income related. This makes for complex administration, since individual or family income fluctuates from one period to another. Finally, copayments make for difficulty in compliance by patients, one effect of which may be unintended loss of benefits, as was reported by Regina Loewenstein.[15]

The HMO or a restructured system

Enthoven and Noll deal with the Health Maintenance Organization and similar organizations at length, and endorse them as the only approach that could replace the perverse incentives of the present health care system. Gaus and Cooper do not deal with the HMO, again perhaps because they do not see it as a major policy option at this time.

In many respects the case for the HMO (more precisely, prepaid group practice) is unexceptionable. It offers the advantage of finessing a major problem in this country, that of the separation, despite their mutually dependent relationship, of the practicing physician and the hospital; it can enhance the status of primary care; and it can bring a critical mass of resources to an underserved geographic area. Perhaps prepaid group practice deserves some compensation for past discrimination against it, both legal and professional.

In certain other respects the case usually advanced for the HMO can be questioned. Most of the savings resulting from the HMO system are in hospital use; and in many prepaid group practices either bed supply is tight or the physicians have limited access to beds. In two path-breaking studies, which are widely cited, the Health Insurance Plan of Greater New York (HIP) reported lower hospital use for its subscribers than in other insurance plans.[16 17] This was despite the absence of financial incentives in this direction, for the plan derived no gains ~~from~~ these savings in the use of community hospitals. The fact is that hospital privileges for its physicians were somewhat restricted.[18] More recently, in the Marshfield, Wisconsin, group practice clinic, as reported by Joel Broida, conversion of part of the clientele from fee-for-service to a prepayment plan did not result in any saving in hospital use; a possible explanation is that the hospital beds were still there to be used.[19] Sometimes the savings yielded by prepaid group practices are overstated, when hospital use outside the system is unreported or differences in the demographic composition of the populations served are neglected.[20] Increasingly it is my impression that substantial regional differences exist among prepaid group practice plans in the use of hospital care, in the pattern of expenditures, and in the resulting savings.

The point of the preceding discussion is that while existing prepaid group practice plans have yielded appreciable savings in hospital use, the confounding factor of tight bed supply may be capable of yielding similar savings in other settings. Whether such savings can be attained through the health planning process is still to be determined, though the evidence for New York State is favorable.

There is a point to be made about the quality of care, which is important in connection with the Enthoven and Noll proposals for steps to be taken by government to enhance the competitive framework. They would do this by developing measures of the quality of care for ambulatory patients and disseminating them in published form among consumers, who would then have a basis for making informed choices among competing health insurance plans. In 1971, Paul Ellwood spoke at the New York Academy of Medicine and thought that such measures might be devised within two years.[21] However, research in this area is still making slow progress. Perhaps such research might be expanded and its pace quickened, but a breakthrough does not seem imminent.

In the absence of measures of the quality of care, the concern that has been expressed over the incentives operating in the HMO toward underservice cannot be taken lightly, once the HMO leaves its traditional bailiwick of socially and professionally motivated boards and physicians caring for a demanding middle-class clientele. Nor is the outcome determinate when small numbers of organized groups of consumers confront small groups of insurance plans or providers; there is no telling in advance whose interests will prevail.[22] The final point is a practical one. Consumers have not rushed to enroll in HMOs. Are legal obstacles the main reason, or is it the unreasonable requirements set by the Congress for the HMO benefits package? Or, is it largely due to the preference of the public to stay with their own physicians? The latter finding was recently reaffirmed by Scitovsky and McCall.[23]

When Enthoven and Noll go beyond the HMO and talk of a new system of fixed prospective payments related to predictable medical need, I have difficulty in grasping their proposal. I can see actuarial calculations by age and by sex, but what about current health status? Further, would the geographic area for which premiums are set be that of the residence of employees or the site of the plant? How complex can the task facing the employer be and still be administratively manageable?

It would be a misreading of Enthoven and Noll to interpret their preference for competitive behavior as an aversion to all forms of state intervention. They merely advance for discussion a whole list of specific steps designed to enhance competition. And some of these steps are not meant to be taken as concrete proposals at this time. Even so, I am perplexed. For example, is community rating to be resurrected and experience rating discarded? In the name of more competition, are we to establish federally financed regional centers to provide tertiary care? Does the mention of a limit on catastrophic expenditures perhaps contradict their prior rejection of more copayment, or does it reflect acceptance of a second-best solution? I understand that some of these questions will be addressed in subsequent work by Enthoven.

Planning and regulation

Enthoven and Noll discuss regulation of health care in the context of formal public utility regulation and reject that as a substitute for appropriate financial incentives. They point out that too many parties are involved in health care; the product and the firms providing it are heterogeneous; the incentives and opportunities to evade regulation (in what they felicitously call "innovative responses to regulation") are many; and the penalties for the regulatory agency's saying "no" may be great, while the kudos, if not rewards, for saying "yes" are evident.

One cannot help but be impressed by the broad case that Enthoven and Noll make against regulation, in terms of both the logic of the argument and the concreteness of examples offered. My own reaction is reinforced by years of observation of the evolving regulatory process in health care. The incentives are often wrong, there is confusion about criteria, simple incompetence is not a rare event, and now and then the sheer arrogance of power is displayed. Too often redress for failure to carry out what was intended is demands for stronger teeth, for a greater grant of authority.

However, in my opinion, the specific case argued by Enthoven and Noll against regulation and planning in health care is not nearly so sound. My own reading of the Hill-Burton program suggests that it was not intended to limit hospital bed capacity; the legislative formula merely set a ceiling on the federal subsidies for construction. Federal hospitals were simply excluded, both by law and by tradition. Large cities would have many beds, because rural residents would receive care there. The burgeoning health insurance movement might serve to increase use; but the threat of vacant beds would serve to enforce financial self-discipline upon individual institutions, and to deter unnecessary expansion.[24] The vast side effects of prepayment were not foreseen in the 1940s.

My plea is, let us not reconstruct history. I prefer to admit that we have changed our minds on what is desirable. Roemer's Law,[25 26] Feldstein's work,[1 4] and the evidence from prepaid group practice[16 17 20] comprise a veritable intellectual revolution. As long as we resist this admission, we continue to have the types of difficulty that Enthoven and Noll ascribe to the special task force of the Institute of Medicine on controlling the supply of hospital beds.[27]

Despite the strong intellectual case advanced against regulation I believe that the types of incentive recommended by Charles Schultze[28] have not yet been devised for health care and tested. Meanwhile, since more copayment is neither desirable nor likely and more competition is not likely and perhaps not so desirable (largely on the grounds that the consumer of health care lacks adequate knowledge), we shall continue to rely on health planning and regulation for the foreseeable future.

Specific proposals for living in a world of health planning and regulation are the substance of the Gaus and Cooper paper. The authors' discussion of planning controls, changes in reimbursement, and direct regulation of market entry is specific and rather technical. Although some reference is made to mechanisms with which we have had some experience, the emphasis is on new, interesting, innovative, and increasingly complex approaches.

Let me declare my bias: I tend to resist large-scale application of the untried and the unevaluated. If an approach has been previously tried, I look for its evaluation. If it has not yet been tried, I prefer to see it introduced selectively, because evaluation stands to gain from variation. I am concerned, too, about approaches that depend on the creation of large data bases in the absence of specification of some of the uses to which the data will be put; this is the one instance in which policy analysts do not count the costs of new technology.

The specific proposals discussed under the heading of planning controls are three — a limit on capital expenditures, expansion of Certificate-of-Need, and restriction of capital financing. The descriptions of the proposals by Gaus and Cooper are to the point, and I have attempted to make my comments equally specific.

Limit on capital expenditures. Gaus and Cooper do not deal with the problem of allocating a given nationwide total amount among the states; surely population alone is a poor indicator. They call for need standards and guidelines, for which adequate need projections, review criteria, and data resources are required. (The words are taken virtually verbatim from the paper.) The projections of need, which I believe we do not know how to make, will presumably go with cost-benefit analyses (that take costs into account while need does not), which we also do not know how to perform when reductions in the death rate are involved. I wonder what general standards can be developed that will preclude wasteful duplication of open-heart surgery in a community and at the same time support needed modernization of facilities? Indeed, what measures exist of the need for modernization? I raise these questions in the context of the Gaus and Cooper paper, but they apply equally to much of the current literature on health planning.

Expand the Certificate-of-Need. Clearly the Certificate-of-Need must be extended to physician offices for large items of equipment. Gaus and Cooper would recertify approvals of existing facilities not fully used and stop approved but uninitiated projects. As a one-time action, I have no objection to the last proposal. But review of all existing programs is bound to be either a myth or an agenda for mechanical, mediocre performance. Also, I wonder about the emergence of a potential liability to compensate for the appropriation of condemned property. This question is most real when capital was borrowed and a loan is still outstanding.

Restrict capital financing. In addition to requiring Certificate-of-Need approval, Gaus and Cooper would impose maximum limits on the operating costs arising from a particular project, and require consideration of available alternative facilities in an area and special consideration of cost-saving institutional mergers. I should like to think that the Certificate-of-Need process would always consider the availability of alternative facilities; and that mergers would be incorporated in the broader considerations entering into the formulation of a Health Systems Agency's health plan. One suspects that the operating costs attributable to a particular project can be manipulated, up or down. Why interfere with management's prerogatives in this fashion?

Cap on hospital revenue increases. Under changes in the reimbursement system, Gaus and Cooper discuss three proposals: a cap on revenue increases; specific procedure reimbursement; and technology-sensitive fee schedules. Along the lines of the Carter Administration's early 1977 proposal, a cap on revenue can raise a hospital's cost consciousness, according to Gaus and Cooper. But they express this concern: Will hospitals make choices that will have the biggest payoff for health? This is a very good example of a broader general question: will the leaders of medicine in this country advance medical research, education, or services? How can the diverse and often competing interests and objectives of the public and of the professions be reconciled? To what extent can payment formulas play a part in this process?

Gaus and Cooper say that ideally they would like to see a prospective reimbursement system which (1) reflects an efficient level of production for each hospital, and (2) incorporates an increase factor for the adoption of accepted technology. In my opinion, if the cost of producing services efficiently were known, a drastic simplification in the way hospital care is paid for could take place. As for the second criterion, an increase factor must involve more than an allowance for new technology. Also to be recognized are the lag in productivity gains in the labor-intensive hospital industry behind the economy at large, and the relative levels of wages currently paid by hospitals for occupations that are comparable with those in other industries.

Specific procedure reimbursement. Gaus and Cooper suggest combining the recent policy decision by the National Association of Blue Shield Plans with written protocols. One is concerned for the patients for whose care reimbursement would be denied retroactively. Perhaps this is not meant as a serious proposal; consider the following quotation from the paper:

> Development of protocols would be extremely expensive and require long implementation time; reimbursement procedures might require more data and more paperwork; perfect protocols could probably never be developed to handle every circumstance, so that flexible application would be needed.

Technology-sensitive fee schedules. The newest proposal is to pay less for unproven technology, thereby limiting the net income of physicians, and to pay more for proven technology. Let us be specific: how would we pay for multiphasic screening? or for mammography? or for a periodic physical examination? Indeed, how would one go about limiting the net earnings of physicians? Nevertheless, for technologies still to emerge and identifiable as separate entities, this may be a handy approach.

Direct market entry. Finally, Gaus and Cooper discuss the FDA model, whereby new technology would be tested, prior to introduction, for both safety and effectiveness. They would add to this the test of cost-effectiveness. One advantage of this approach, they note, is the accumulation of a rich data base. Against it are the additional expense of research and development and delay in the adoption of new technology. I ask: What is to be learned from our experience with the development of new drugs since 1962? In this context, I take it, cost-effectiveness analysis really means cost-benefit analysis. In light of my earlier comments on the practicability of cost-benefit analysis in health care, how would such analyses be performed?

Physician and consumer education

Gaus and Cooper propose that physicians be educated and trained to be cost-conscious and that consumers be given the facts about the cost and effectiveness of various diagnostic and treatment procedures. In principle, no one can object to having physicians learn about the economic consequences of their decisions on behalf of their patients. I doubt that it would make much difference in what they do. In any case, I lack competence to advise on the contents of the medical school curriculum.

As for educating the consumer, my impression is that at the time of illness most patients will say that price is no object. I recall that when voluntary hospitals in New York City tried to protect patients against overcommitting themselves financially, the patients were willing to pay more for hospital services than the hospitals proposed to charge. Let me also express the doubt that at the time of illness, a patient, having chosen a physician, would want to know just how uncertain that physician was about diagnosis or treatment.

Summary

According to the estimates presented here, one-sixth of the increase in expenditures for short-term hospital care in the decade 1966-76 is due to a rise in utilization. Included is a small allowance for the aging of the population. Five-sixths of the increase is due to the increase in cost per adjusted patient day. In turn, my estimates indicate that approximately two-thirds of the increase in patient day cost is due to increases in the prices of inputs and one-third is due to increases in the quantity of inputs or intensity. These estimates represent appreciable differences from findings reported or cited by others.

Whatever its magnitude, an increase in inputs or in intensity is not tantamount to an increase in technology. Neither the papers by Enthoven and Noll and by Gaus and Cooper nor my own calculations yield an estimate of the contribution of changes in technology to the increase in hospital care expenditures. This task still remains to be done, item by item. It is important to recall, moreover, that the relative contribution of an increase in a given factor to an increase in total expenditures depends not only on its rate of increase but also on its size in the base year.

It may be true, as the two papers seem to suggest tacitly, that public policies on health care technology need not differ from public policies concerning other types of input. However, it is likely that different types of technology may call for different policies.

I agree with Enthoven and Noll that more copayment is neither a desirable nor a practical policy alternative at this time. In this connection data have been cited above on the trend in third-party payments as a proportion of hospital care expenditures and on the increase in the proportion of patient days reimbursed at cost before and after 1966. The magnitude of the change in cost reimbursement was far greater than that of the change in prepayment. In my judgment — which many other observers do not share — the former probably made the larger contribution to the marked acceleration in patient day cost that began in the first year of Medicare and Medicaid.

The discussion in Enthoven and Noll of the HMO and other, competitive forms of health care delivery is lucid and logical, but not necessarily persuasive that they are a major policy option for the foreseeable future. In my judgment the savings in hospital use associated with prepaid group practice have typically been confounded by a tight bed supply and may be attainable, at least in part, in other ways; the lack of measures to monitor the quality of care for ambulatory patients continues to be a serious weakness; and so far consumer acceptance has not been demonstrated on a large scale.

Physician and consumer education on costs may be worthwhile in themselves, but are not likely to serve as sources of appreciable savings in health care expenditures.

For the foreseeable future it will be necessary to rely in major ways on health planning and on prospective reimbursement arrangements.

Comments

Some of my own views on health planning and on reimbursement follow.

With respect to health planning, the criterion of need is not consistent with the performance of cost-benefit analysis; and, as noted above, Roemer's Law raises still further difficulties for the criterion of need. I would rather say, we have changed our mind: no longer do we consider that more hospital care is necessarily better.

A principal problem in health planning is how to effect a curtailment in the supply of resources. For big, visible pieces of equipment the Certificate-of-Need process is available. The questions are: Can it be timely? Can it operate fairly? What is required to make it effective?

To control steady, incremental technological creep it will be necessary to rely on prospective reimbursement. Considerably less understanding and information are required to deal with changes in rates over time than with variation in rates at a given time. Some regulatory authorities do not consider this distinction.

However, it is only fair to acknowledge that after some interval automatic reimbursement formulas cease to work. It then becomes necessary to negotiate with individual hospitals. A body of experience with this process is just beginning to emerge.

I have come to believe that a single reimbursement formula should apply to a hospital, regardless of the number of sources of payment. The rate-making authority must not be affected by the conflict of interest that a third-party payer has in keeping down its own rate of payment.

It is perhaps surprising that one of the foremost complaints about prospective reimbursement in New York State, where it was enacted in 1969, is that before the fall of 1977 it had not really been tried. Too often it was applied retroactively and without notice.[29] Sound internal hospital management was thereby impeded.

Both in health planning and in regulating rates it is important that the process be seen as open, fair, and trustworthy. On the positive side of regulation, there must be a steady display of competence by the regulatory authority; on the negative side, any temptation to exercise power arbitrarily should be resisted.[30]

Both health planning and rate regulation are to be carried out below the federal level.[31] The responsibilities and authorities of the state and local levels respectively are still to be delineated, as well as the amount of discretion allowed to them by federal laws and regulations.

In planning and regulation the roles of professional and other voluntary, mediating institutions remain to be considered. The social costs such institutions impose are often lower than those imposed by governmental agencies.[32] But their legitimacy in carrying out mandatory public policies is sometimes questioned.

Finally, I prefer to see constancy in goals and stability in policies and practices. Applying and frequently modifying half-baked regulatory measures may prove to be more dangerous than adopting half-way technologies in diagnosis and treatment.

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Report of the symposium August 1–5, 1977

Health care is a pressing social and political issue in the United States. Proposals for change in the organization, financing, and provision of personal health services are being made with increasing force and frequency.

The Sun Valley Forum on National Health, a nonprofit institution, was established in 1970 to pursue educational activities concerning various aspects of the nation's health care system. In June 1971, the Forum addressed a major symposium to the financing of the nation's health care system. In June 1972, the Forum turned to the question of the organization of the nation's system for delivering medical care. The 1973 symposium considered issues related to primary care. The symposium held in August of 1974 reviewed Canada's experience with its national health insurance system. A symposium in early 1975 dealt with the position of the foreign medical graduate in the American health system, while a second in the summer dealt with child health care.

In the summer of 1977, the Forum held a symposium on the topic "Technology and the American Health Care System: Is Technology the Culprit in Rising Costs?" For this symposium, the Forum commissioned leading experts in health care services to prepare and present papers on key questions related to the topic of the symposium. The forty-two participants in the symposium included practicing physicians, academicians, medical care specialists, economists, administrators, government officials, members of the press, and lawyers. A list of the participants appears in the early pages of this volume.

This report, prepared at the close of the 1977 symposium, was reviewed by the participants. No one was asked to sign the report, and it should not be assumed that any participant subscribes to every statement appearing in it. But except where it indicates that a participant accepted the opportunity to dissent or to express a separate opinion, the report represents the sense of the symposium.

Introduction

In this century, the American health care system has witnessed and been a party to massive technological change. Through the fruits of a vast biomedical research enterprise and ordinary technical evolution, medicine has developed new techniques, and life-saving and life-prolonging technologies that have transformed diagnostic procedures and treatment practices. Government has fostered this technolgical development through sustained financial support of research, education, and patient care, a policy choice enthusiastically endorsed by the public; private philanthropy and industrial research and development, also have made important contributions.

In the last decade, the cost of medical care has risen at an alarming rate, about twice the general inflation rate. National health expenditures totaled $42 billion in fiscal year 1966; for the year ending June 30, 1977, the total was about $160 billion. So far this expenditure explosion has proven intractable. The public price tag for Medicare and Medicaid alone is approaching $50 billion per annum, and the annual cost increases in these two programs approximate the annual spending in the remainder of the Department of Health, Education, and Welfare's health budget.

The problem of rising costs stems from several recognized sources, including general inflation, changes in medical practice, increases in population, per capita use, and wage structures. But in recent years some voices have begun to argue that technology and technological change are major culprits in the cost spiral. The 1977 symposium of the Sun Valley Forum on National Health was convened to evaluate that contention.

Technology

Technology is an all-embracing term. Rational discussion of policy questions regarding technology is often impeded by the fact that the term has different meanings to different persons. Technologies can be characterized by their medical objectives, their capital and operating costs, their effectiveness, and their safety (or risk). A few points are important:

1. Growing technological complexity is not unique to the medical care system. All sectors of industrialized society have reflected increased dependence on complex and costly production processes.
2. While all means for producing and delivering medical care are technology is some sense, "new technology" usually refers to changes associated with new capital equipment, new medical and surgical procedures, and new drugs.
3. The potential cost impact of a new technology can be associated with its medical objectives.

   a. Therapeutic technologies directed at cure imply a limited period of resource use. Those directed at the management of illness, however, imply on-going involvement of the patient with the medical care system and thus a long-term cost impact. Benefits from these technologies depend upon the disease or disability being treated and the efficacy of the technology in reducing that illness. At the extreme, technologies that extend survival without cure place a high cost burden on the system without necessarily generating compensatory benefits.

   b. Diagnostic technologies present a distinct set of problems from the standpoint of cost impact. Unlike therapy, which is usually directed to the known, diagnostic technologies are addressed to the unknown. For the undiagnosed disease, tests are often an open set without externally imposed limits. Indeed, the more a series of tests yields no answer, the more reason is provided to conduct more tests. Advanced diagnostic measures can, of course, reduce the need for more expensive procedures, such as exploratory surgery. But new diagnostic technology which is developed for a particular disease is often applied more widely as it becomes more available. And, in the absence of real limitations on availability, an ever-increasing expansion of diagnostic tests will be induced by hope of benefit and by concerns about malpractice claims if the tests are not pursued. Greater use of new diagnostic technologies is further encouraged when, as is often the case, they entail little or no risk to the patient, and when high volume leads to low unit cost.

c. Technologies directed at prevention, early detection, and rehabilitation have the potential to generate true cost reductions. Advances in the 1940s and 1950s, for example, prevented diseases such as diptheria and polio and reduced the need for expensive institutionalization for patients with tuberculosis. But since such technologies often operate outside the system for delivery of medical care, they may not benefit from our current reimbursement system. Thus, some important cost-saving technologies are not the objects of adequate financial investment. A sound policy of managing medical technology would pay far more attention to those technologies outside the medical care delivery system that emphasize prevention, detection, and rehabilitation.

4. It is important to distinguish between the capital costs associated with new technology and the impacts of new technology on continuing use of resources in the medical care system. Public awareness is focused on "big-ticket" high capital cost technologies. But many technologies that call for modest capital cost generate significant continuing use of resources by requiring increased personnel and supplies and by stimulating increased levels of utilization within the system.
5. Technologies that are directed toward improved management of the medical care delivery system rather than to the clinical condition of patients have significant potential for reducing the cost of care. Such managerial improvements should be included among the candidates for new technological development.

Preliminary comments on issues other than cost containment

The predominant issue in the current debate about medical technology is cost, and the balance to be struck between the cost of new technology and its benefits. Most of the symposium was addressed to this question.[1] But a

[1] New technology may also, of course, lead to indirect social costs and societal dislocations that are of greater importance than direct dollar costs, but that would be the subject of another symposium.

number of other policy questions also bear upon the general subject of health care technology. Though these questions were not pursued in detail at the conference, some comments should be made about them before cost containment, the next subject of this report, is addressed.

As a starting point, improved technologies have made a major contribution to relief from illness. Much medical technology is good, and continuing research is crucial to the future development of medical care. The federal government should continue to play a major role in encouraging such research and development.

In addition, the federal government's role should include a responsibility to assure that new medical technologies are not introduced into medical practice until they have been tested and shown to be reasonably safe. The Medical Devices Amendment of 1976, amending earlier legislation, vests responsibility for this function in the Food and Drug Administration and represents a step in this direction. It is too early to evaluate the effect of this new law.

Next, the federal government, producers, and health care providers all have a responsibility to see to it that medical technologies employed in the field are reasonably effective as well as safe.[2] For this purpose, it would be desirable for an appropriate federal agency to assemble and evaluate data on the effectiveness of medical technologies in use and to disseminate the results of such analyses to consumers, planners, third-party payers, and health providers. (For the relevance of this point to cost containment, see the section "Technology and cost containment," question four.) The federal agency that gathers and disseminates data on the effectiveness of medical practices should also take the initiative to disseminate information about rehabilitation and medical management systems (which do not command the attention they deserve in the health care community), as well as information to consumers evaluating medical technologies that are is use.

Finally, all of the analysis and prescription about medical technology is crippled by the scarcity of data on matters such as emerging new technologies,[3] actual use of technologies in the field, true costs and charges for technologies in use, radiating impact of technologies upon medical procedures and practices, etc. Selective information on these and related matters should be assembled, analyzed and published periodically by an appropriate governmental agency.[4]

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[2] Participants Banta and Lee believe that this paragraph and the preceding one should be combined to emphasize their view that safety and efficacy are interrelated and that, since all medical technologies have risks, safety can be assessed only in relation to anticipated benefit.

[3] Participant Marks believes that there are many data but that they generally are of a nature that does not permit decisions as to the applicability of the technology because the science base (basic and applied) is incomplete.

[4] Participant Rettig is of the view that greater clarity of concept and purpose is needed about medical technology before significant data collection about it is initiated. "Measuring and balancing costs and benefits," second statement.

Technology and cost containment

Technology as such is pervasive in modern medicine, is generally constructive, and, where safe and effective, should be encouraged. But four questions remain:

First, to what degree does the continuous infusion of new technology increase the aggregate costs of medical care?

Second, how can the benefits, costs and risks of new technologies be evaluated?

Third, what balance can be struck between these costs and benefits?

And fourth, where it appears that the costs of new technologies (or some of them) exceed their apparent benefits, what techniques of social control would be most effective to bring costs and benefits into balance?

In short, is the health care system as a whole paying too much for recent technology — so much that it cannot reasonably be afforded — and, if so, what if anything should — or can — be done to correct that situation? How can the use of modern medical technology be optimized?

Measuring and balancing costs and benefits

1. Cost measurements are available for a few particular medical technologies, such as laboratory tests and radiology, but the cost of medical technology in the aggregate is not easily measurable. Available data on the increase in hospital care expenditures during 1966–76 measure only the contribution of increased utilization, prices and earnings, and resource inputs; they do not measure the specific contribution that technology made to the increase in cost levels. While some new technologies in medicine represent genuinely new capabilities, others simply replace older ones. Some new technologies are cost-reducing; a correct measure for assessing the economic impact of technology on costs of the system would net out those savings. To some substantial degree, moreover, increased costs that are imputed to a technology itself are often in fact attributable to excessive or other inappropriate use of it, rather than to its valid and appropriate use. And some increased cost is attributable to the extension of use of a technology to a newly discovered valid application, or extension to new populations of patients. Although the methodology of economic measurement is thus subject to challenge, and data are limited, incremental hospital care cost attributable to technology over the past decade is believed to be in the range of 20 to 40 percent.[5]
2. We have yet to quantify the aggregate benefits, or disbenefits, produced by the introduction of new medical technologies over any given time span.
3. What has not been done in the aggregate has, in some instances, been at least partially done in the particular — i.e., to collect data about a

[5] Participant Klarman does not believe that the aggregate data available provide a sufficient basis for this statement.

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particular technology, to calculate its cost in application, and to assess the health outcomes and improved diagnostic results that it produces. So far, however, few such analyses have been made.

4. Even when such studies are made, moreover, it must be recognized that the ultimate question, whether the health and diagnostic outcomes are "worth" the cost, must be a value judgment.

Diagnosis of the cause of cost increases

Despite difficulties of measurement, there is an increasing sense among informed observers that more is being spent for technologically related activities than can be justified by their medical benefits. If so, how should the rate of increased use of new technology be slowed? The means of social control chosen must be related to the process sought to be controlled. If recent technology has, in fact, produced a significant increase in the aggregate cost of medical care in the United States, by what process has that come about? The answer is that, as a generalization, new technology as such does not significantly boost costs; it is the *behavior* of individual persons and human institutions — the *way* in which they use the new technology — that leads to the cost rise. This distinction is central to rational policy analysis.

• At root, new medical technologies are adopted and used because physicians, scientists, hospitals, patients, and political leaders are all predisposed to encourage their use and virtually nothing deters them.

• Under present payment systems, hospitals and physicians often benefit financially from the use of new technologies. The Hippocratic Oath, the desire of the patient to obtain the best available care, pressures of the malpractice threat, the technologically oriented ethos of the twentieth century, widespread third-party payment systems, the salesmanship of the manufacturers of new technology all point in the same direction and create the same predisposition, grounded in a repugnance to setting a price on human life and insulated from cost consequences: "If a new, apparently safe and beneficial technology appears — use it!" Other things being equal, new technology that is medically promising will always be promptly adopted unless active disincentives exist that slow the process of adoption.

• Are such disincentives in place in the present system for health care payment in the United States? Regrettably, they are not. Hospitals operate on close to a full cost-reimbursement basis through governmental programs or private insurance plans. Doctors are paid today in largest part not by patients but by third parties — the government and insurance companies — on the basis of fees charged by the practitioners, and the fees themselves are largely uncontrolled. Payment for diagnostic tests and other ancillary services in the hospital are reimbursed in the same way. The amount and kind of medical services provided are largely at the discretion of the practitioner, not of the patient or the third-party payer. The patient has little economic incentive to keep down charges for medical services and typically has even less ability to make an independent judgment as to the quality of, or need for, the service provided.

• If technology contributes to the aggregate cost of the medical care system of the nation, it is not because of something peculiar to technology. It is for the same reason that other factors contribute to the escalation of medical care costs — namely, that there is little at work in the system tending to keep costs down, while at the same time the Congress and private purchasers of medical insurance have so far been willing to pour dollars into the system, either directly or by tax subsidy.[6]

Changes in the provider reimbursement system

The conclusion that flows from the preceding paragraphs is that one way to address the cost increases attributable to new medical technologies is to build incentives for cost containment into the medical care payment system. How could this be done?

1. The Carter Administration proposes to impose a national ceiling on hospital capital spending as well as a tight limit (determined by a universal percentage increase over the preceding year) on the total revenues of each hospital. It is intended that this mechanism of limited funding compel each hopspital to establish, for the first time, internal machinery for setting priorities among different expenditure demands.

This approach has some promise, at least for the short run.[7] It must be recognized, however, that its impact will be limited, since it does not cover all hospitals, and since hospitals account for less than 50 percent of medical care expenditures.[8] The impact this approach would have on the adoption of new technology is speculative.

2. Another suggestion is that hospitals be required, in advance of each operating year, to negotiate with the government a prospective reimbursement budget — and then live within it. This approach is more hand-tailored than the universal percentage cap, and difficult to administer. Prospective reimbursement has not been subjected to a full test in the United States, but experiments with it are under way and should be continued.

3. A major portion of aggregate health care spending is attributable to charges made by physicians and by providers of auxiliary services. Short of direct fee controls, it would be possible for the federal government to develop

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[6] Participant Rettig would qualify this point by noting that one form of new technology is the capability to perform tasks that were previously beyond reach, as distinct from the capability to perform current tasks more efficiently or in a marginally better way. To the extent that genuinely new capabilities created by technical change require increased inputs beyond current inputs, new technology causes increased new costs. These cost increases are not behavioral in origin; they result from the new capability and a determination that the additional resource requirements are worth it. One factor driving technical change is the desire to expand current capabilities to deal with problems that are at present intractable.

[7] Participant Dunlop does not agree, since he believes that it will prove impossible to administer the expenditure cap, allocated by formula or by bureaucrats to states, localities, and individual hospitals. Participants Enthoven and Sanders share this concern.

[8] Participant Noll also points out that hospitals may respond to a cap by unbundling some services and pushing them back into the physicians' offices.

schedules to limit the amount which the government would pay to the provider for each designated medical service, or at least for each new one. Private insurers would doubtless follow suit. This approach would encounter problems both in application, as, for example, in defining and enforcing the unit of service upon which the schedule is based, and because of the continued ability of providers to expand services. The organized health professionals would also oppose it bitterly. Nonetheless, it has considerable appeal as a practical mechanism for cost containment.

4. A point deserving particular mention is that the limited fee reimbursement approach just discussed could effectively be linked to the proposal discussed in the section "Preliminary comments on issues other than cost containment," regarding data collection and evaluation of medical technologies. The physician limited fee reimbursement mechanism, once in place, would provide a mechanism that would effectively discourage practitioners from using medical procedures that are found by experience to be ineffective or to produce only marginal benefits at high costs.

5. It would, of course, be possible to combine the cap approach for hospitals with a limited reimbursement fee schedule approach for health practitioners. A substantial impact on the rate of rise in national health care expenditures would probably result.[9] The organized professions contend that this approach would have a negative effect on the quality, character, and availability of health care; that contention is, however, certainly debatable.

6. In the view of some, the best long-term solution to the problem is to introduce a fully effective competitive environment into the field of health care by completely restructuring the delivery system away from the traditional solo practitioner fee-for-service basis. The central concept would be to deliver health care through organized health care delivery systems in which physicians would have incentives to control costs, with payments aided by a national insurance voucher plan. Under such a scheme the economic incentives of the traditional medical care system would be reversed—i.e., health maintenance organizations (HMOs) and similar organized systems would compete among themselves and with the rest of the system, consumers would choose their own provider, the income of physicians would not rise directly as a function of increases in the cost and amount of services performed, and the cost risks would be shared by the health providers.

[9] Participants Enthoven and Noll do not believe that price regulation can effectively combat the rise in medical care costs in the long run. In their view, price regulation has been ineffective when tried elsewhere in the past; in industries with numerous producers, price regulation has generally served to limit competition, to reduce introduction of cost-saving innovations, and to protect inefficient producers. Further, they think that price regulation in the medical-care field would chill the growth of prepaid group practice and other institutional innovations that have the greatest promise for cost reduction. Participant Lee concurs in this general point, but nonetheless feels that short-run considerations may make price regulation necessary.

By two different statutes, the government has sought to promote the growth of HMOs.

Existing laws and regulations should be revised to go further to encourage the spread of the HMO concept. But it must be recognized that the road to a full reorganization of the nation's traditional health care delivery system would be long, difficult, and embattled.

7. Some proponents of national health insurance believe that their own favored plan would have the collateral advantage of containing costs of the medical care system. Opponents, and some other proponents, dispute this. The symposium participants did not debate the complex perennial topic of national health insurance, viewing it as collateral to the technology issues before the group.

Regulatory controls

The approaches just reviewed seek to deal with the "technology problem" by addressing the broader underlying problem of uncontrolled costs arising from our present system of reimbursing medical care providers. The propositions that follow deal with proposals to use direct regulation to respond to the phenomenon of new technology. (Whether any of these proposals could command the degree of political consensus that would be required to make them effective is not evaluated here.)

1. The most direct approach would be to try to impose a moratorium on technological advance and its introduction into use. This approach is both undesirable and certain to fail.

2. Rational use of new technology would be substantially enhanced by guidelines, issued by the federal government and developed through a process of concensus among interested groups, that would assist decisions on whether new pieces of equipment or procedures are safe and efficacious, how many should be acquired, and who should get them. Information and advisory standards thus developed should be made available to public sector purchasing agents, PSROs, Blue Cross-Blue Shield, private insurance companies, and consumer purchasers of private insurance, to help them determine what new and existing technology should be covered or purchased in their programs. Such information should also be made generally available to the public. At each stage in the evaluative process, opportunities should be provided for consumer input. Finite standards and assessment for each technological advance would be difficult to develop, but the effort could be productive.

3. State and local community planning agencies or health system agencies can make a contribution toward constraining the excess diffusion of expensive technology. Guidelines of the sort just described could be helpful to such agencies. Experience to date would indicate, however, that local health planning agencies tend to approve most applications made to them because they have little incentive to say "No." They are not spending

their own money, and they usually are subjected to heavy community pressure in favor of purchasing the newest equipment.

4. Direct regulation of technology at the point of entry to the market is an approach that has been tried. The Food and Drug Administration regulates food, drugs, cosmetics, and (since 1976) medical devices, by requiring, through variety of evaluative procedures, federal scrutiny and approval before such items can be introduced to the market. Some have suggested that this approach be extended to medical procedures as well. This avenue is not, however, recommended. The cost would be very high, and it is unlikely that the FDA could obtain the resources to carry out the task adequately. Enormous difficulties would be encountered in the attempt to define and identify individual procedures. More fundamentally, governmental regulation is inherently a limited tool, and invariably subject to political interference when it undertakes to take action that is politically unpopular, as recent experience with laetrile and saccharin well illustrate.

5. A national dollar limit could be imposed on hospital expenditures for capital goods, including high-cost technologies, so that a hospital could not purchase such a technology without a Certificate-of-Need process which hitherto has been lacking. This plan would reach only big-ticket technology items bought by hospitals. Little technologies and purchases by doctors' offices would not be reached. But such a national control would force some degree of priority setting in the diffusion of costly technologies.

6. Earlier discussed was a proposal for a federal agency to assume a direct responsibility in assembling, keeping track of, evaluating and publishing analyses of medical technologies and practices in use. It is also pointed out that this approach would gain major leverage by being coupled with limits on reimbursement to health care providers for particular services or procedures. This combined mechanism would in fact be a form of direct regulation of technology, but one that did not suffer the bureaucratic disadvantages of the FDA model and would have the major advantages of being less coercive and based on actual experience with technologies as applied in a real environment.

Other approaches

Besides changes in the payment structure of the health care system and the introduction of direct controls regarding technology, other supplemental long-term approaches should be mentioned:

1. As change comes to the structure and payment system of health care, corresponding change and postdoctoral programs in medical schools could help prepare health care providers for later supportive participation in the new system.

2. Control of supply, as by constraining the supply of physicians and hospital facilities, especially hospital beds, is a possible strategy.

3. Consumer education campaigns could help public understanding of the efficacy of existing technologies and mitigate unrealistic public expectations from new technology.

4. In future, any federal agency that makes grants in support of biomedical technology development should, in evaluating a research proposal, consider it to be a negative factor if the agency were to estimate that a successful outcome of the proposed research would develop a new technology that would have a high potential escalatory impact on health care costs without yielding benefits worth the cost.* The federal government might also seek to target its research support on technologies with a potential for reducing costs.

Nutshell summary

• Medical technology *per se* is not the culprit behind rising costs in health care.

• The real problem underlying the soaring rise in the aggregate cost of the nation's health care system is the virtual absence in the system of incentives for containing costs. To deal with this problem, it is necessary to install such incentives. Various ways of doing this have been suggested, such as hospital budget caps, limits on federal reimbursement rates per service, and competition of prepaid plans with each other and with other forms of medical care delivery. In the short run, hospital budget caps would be useful, but in the long-run fundamental changes are required in the present payment system.

• To advance the safety and efficacy of new medical technologies and procedures and of those already in use, the federal government should assume a greater responsibility for an ongoing gathering, assembling, evaluating and disseminating of data and analysis relating to such technologies and procedures.

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*Participants Rettig, Marks, and Lee do not concur in this sentence. In their view, the greatest share of research grants involves outputs that are remote from near-term application in medical technology; furthermore, prediction of the outcomes of research is uncertain. Introduction of this issue in research applications would thus be meaningless relative to its intended objective and merely add to the cost of preparing and reviewing proposals and justifying award decisions. It is possible that investment decisions on research and development programs might be made in the light of expected cost impact, but even that would be difficult.

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